US009295494B2

(12) **United States Patent**
Strauss et al.

(10) **Patent No.: US 9,295,494 B2**
(45) **Date of Patent: Mar. 29, 2016**

(54) **SPINE STABILIZATION SYSTEM**

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(73) Assignee: **K2M, Inc.**, Leesburg, VA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 243 days.

(21) Appl. No.: **13/636,416**

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§ 371 (c)(1),
(2), (4) Date: **Nov. 8, 2012**

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PCT Pub. Date: **Jan. 12, 2012**

(65) **Prior Publication Data**

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Related U.S. Application Data

(60) Provisional application No. 61/359,028, filed on Jun. 28, 2010.

(51) **Int. Cl.**
A61B 17/70 (2006.01)
F16D 1/00 (2006.01)
A61B 17/88 (2006.01)

(52) **U.S. Cl.**
CPC ***A61B 17/701*** (2013.01); ***A61B 17/70*** (2013.01); ***A61B 17/7002*** (2013.01); ***A61B 17/8863*** (2013.01); *A61B 17/7035* (2013.01)

(58) **Field of Classification Search**
CPC A61B 17/7004; A61B 17/701
USPC 606/261–262, 264–270
See application file for complete search history.

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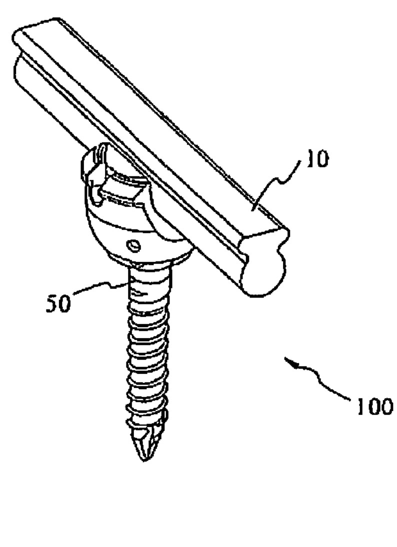
Assistant Examiner — Stuart S Bray
(74) *Attorney, Agent, or Firm* — Carter, DeLuca, Farrell & Schmidt, LLP

(57) **ABSTRACT**

A spinal stabilization system includes a connecting rod, a rod bending device, and a plurality of bone screws. The connecting rod includes an elongate round portion, an elongate head portion and a neck portion connecting the elongate round portion with the elongate head portion. The rod bending device includes an elongate body defining an aperture configured and dimensioned to receive the connecting rod therethrough in a single orientation. The bone screws include a housing portion and a screw shaft distally extending from the housing portion. The housing portion includes an inner housing and an outer housing slidably surrounding at least a portion of the inner housing. The inner housing defines a slot configured and dimensioned to releasably secure the elongate round portion of the connecting rod therein. The outer housing is movable relative to the inner housing between an unlocked state and a locked state.

32 Claims, 33 Drawing Sheets



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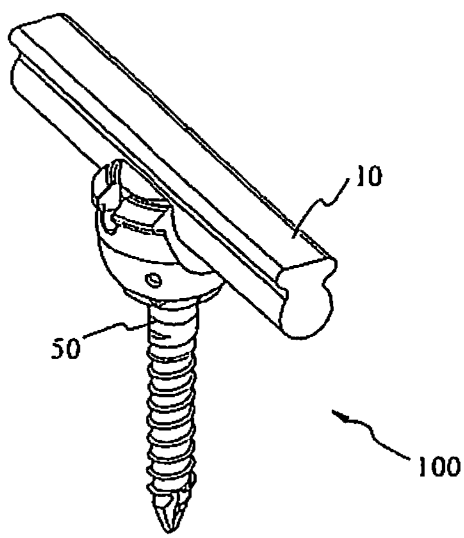


FIG. 1

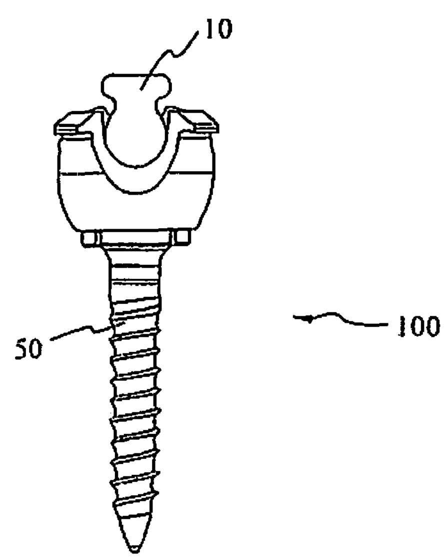


FIG. 2

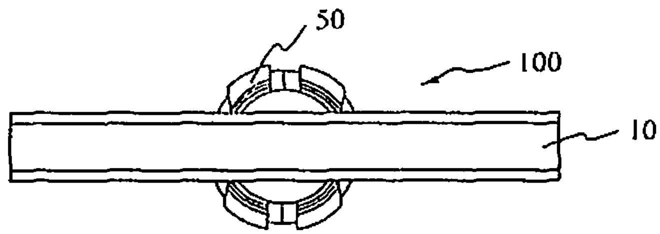


FIG. 3

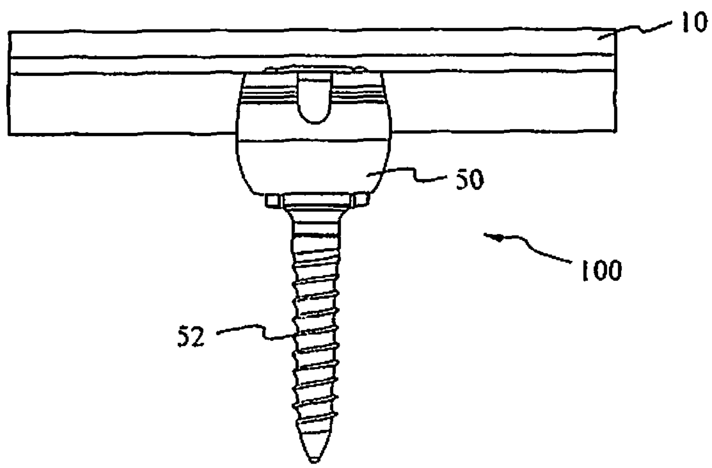


FIG. 4

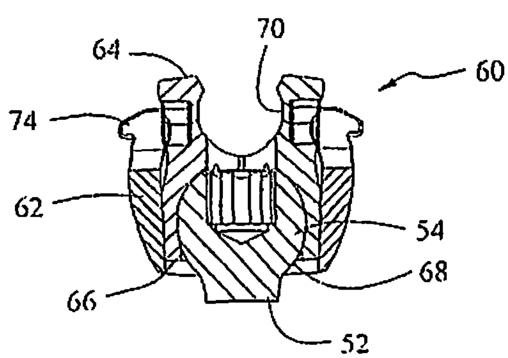


FIG. 5

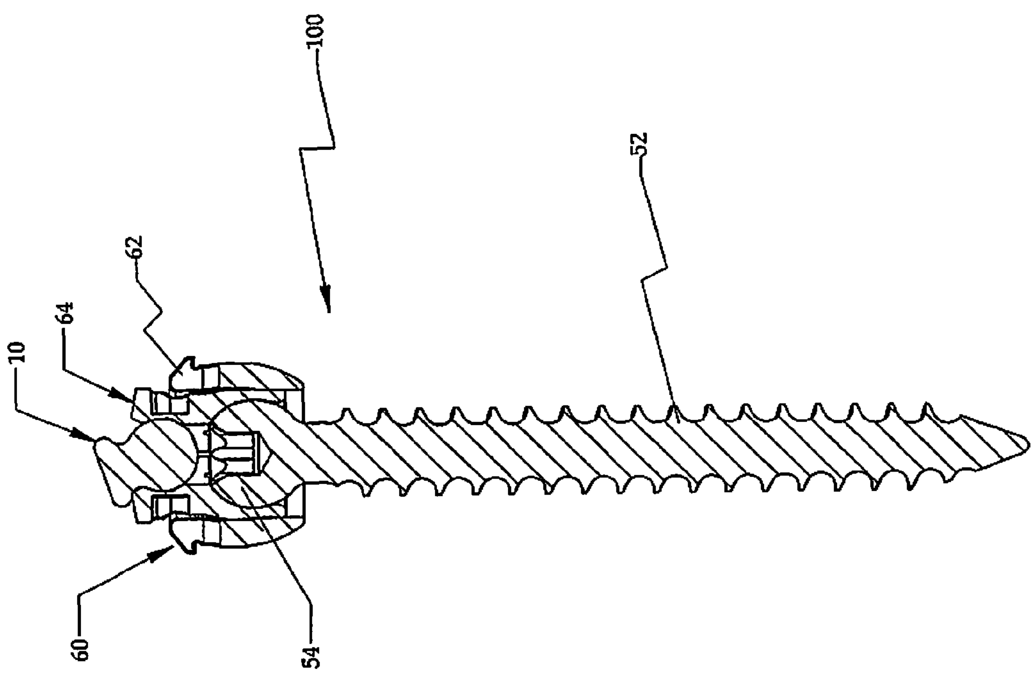


FIG. 5A

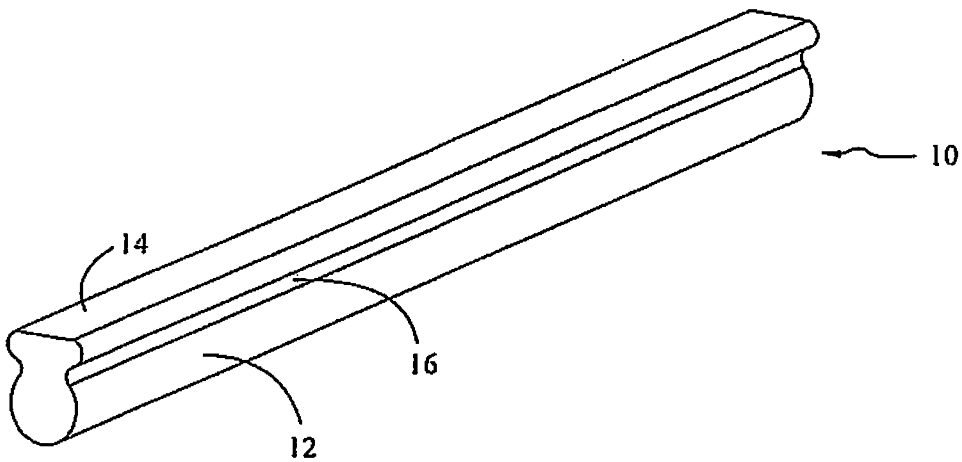


FIG. 6

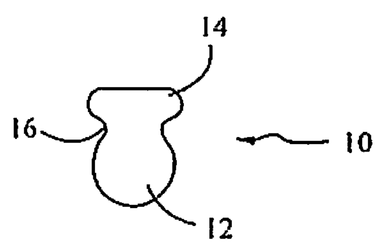


FIG. 7

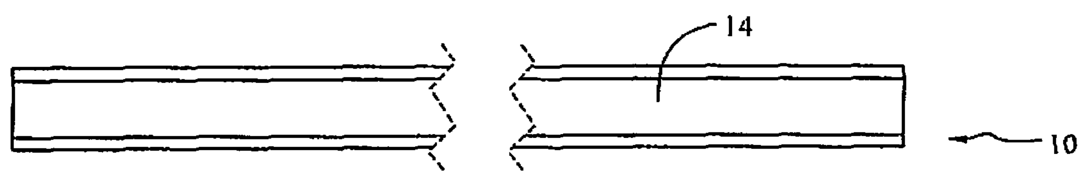


FIG. 8

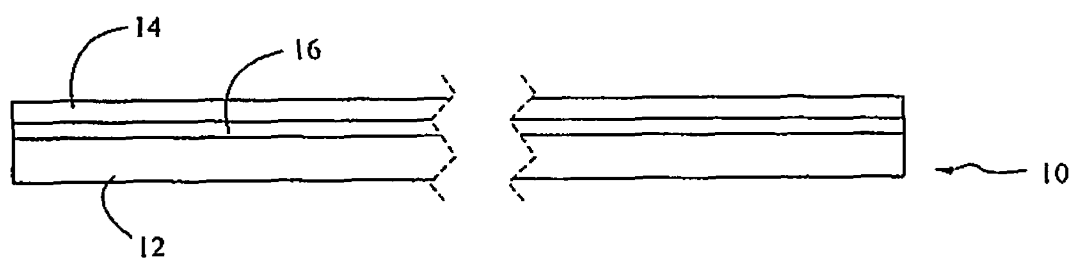


FIG. 9

Rod Deflection Comparison
Based on Material

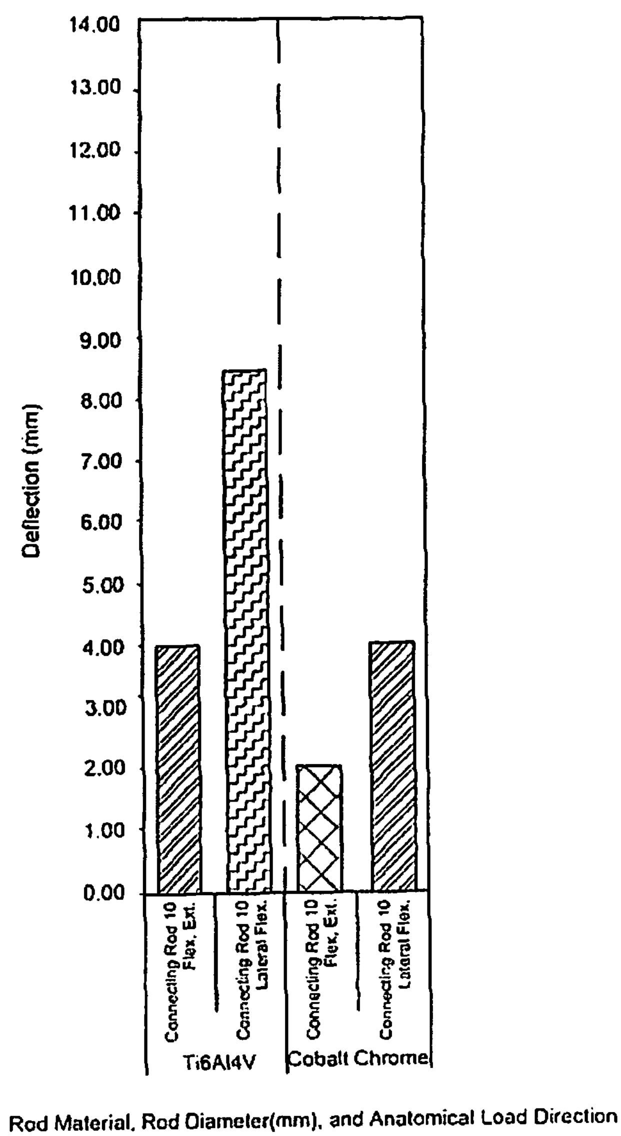


FIG. 10

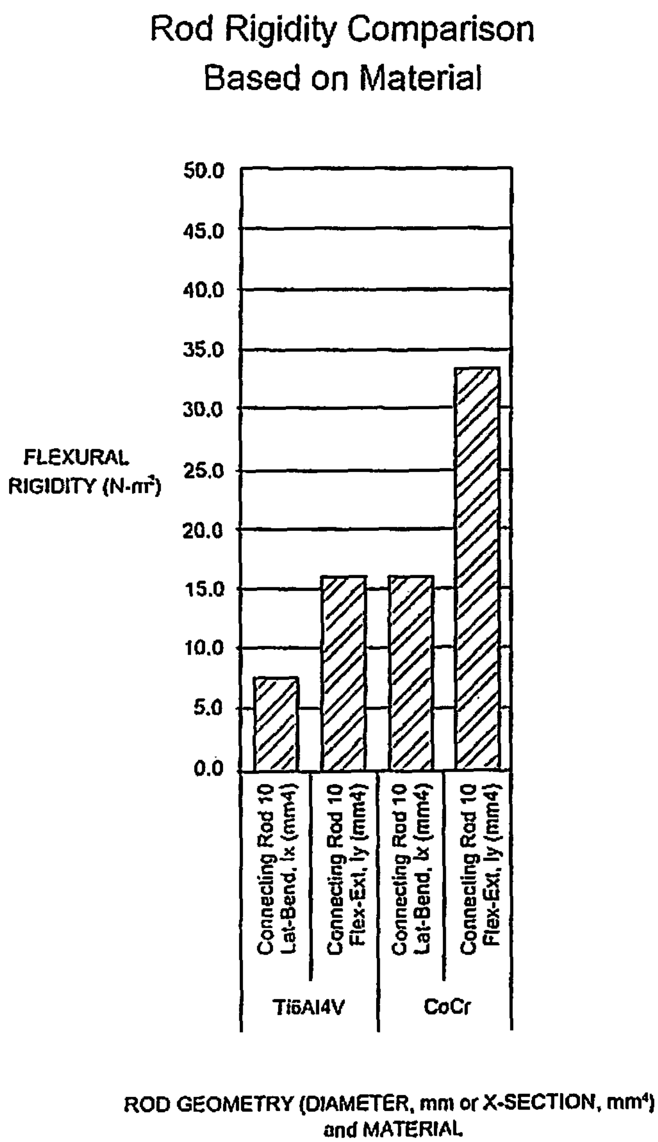

Rod Rigidity Comparison
Based on Material
FLEXURAL
RIGIDITY (N-m²)
50.0
45.0
40.0
35.0
30.0
25.0
20.0
15.0
10.0
5.0
0.0
Connecting Rod 10 Lat-Bend, Ix (mm4)
Connecting Rod 10 Flex-Ext, Iy (mm4)
Connecting Rod 10 Lat-Bend, Ix (mm4)
Connecting Rod 10 Flex-Ext, Iy (mm4)
Ti6Al4V
CoCr
ROD GEOMETRY (DIAMETER, mm or X-SECTION, mm⁴)
and MATERIAL

FIG. 11

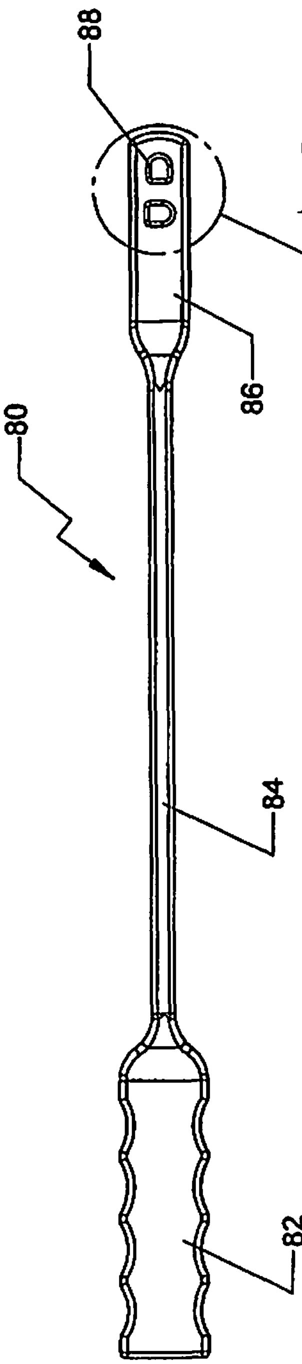


FIG. 12A

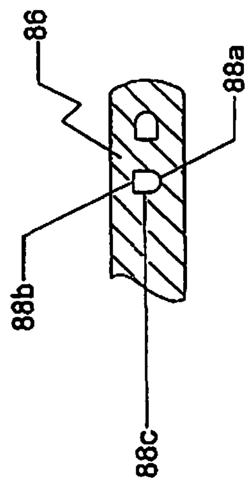


FIG. 12B

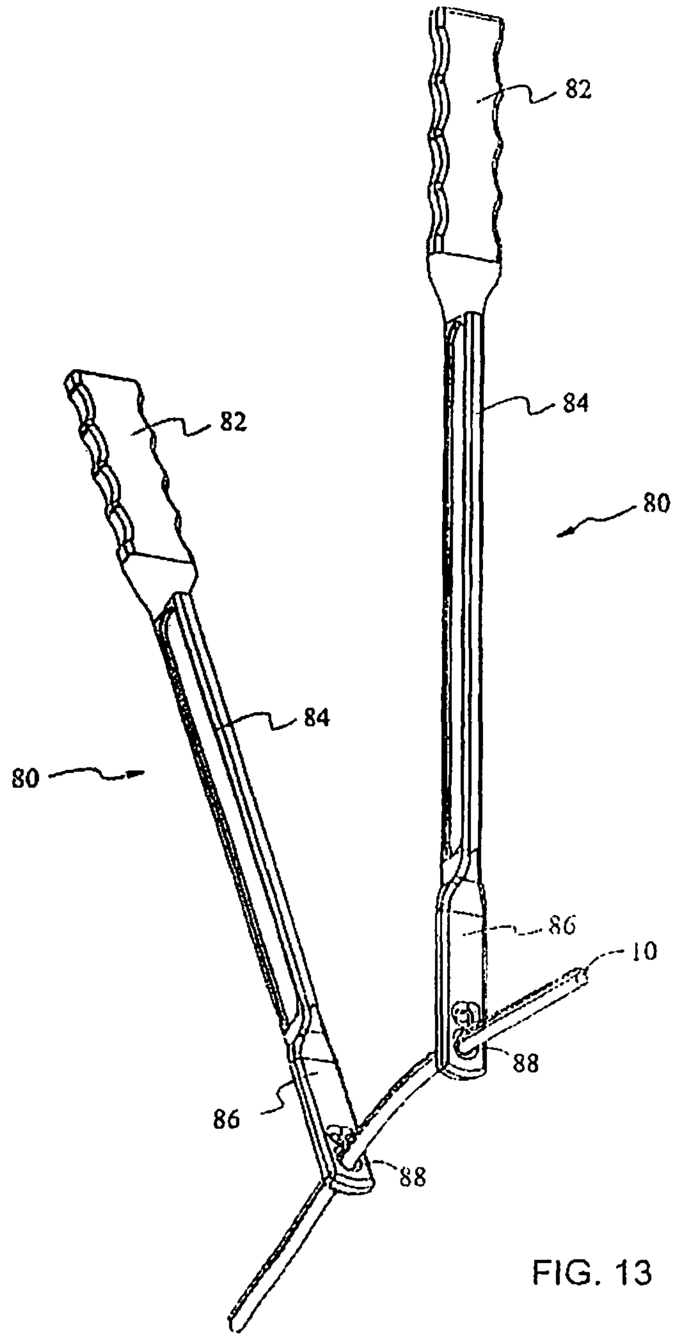


FIG. 13

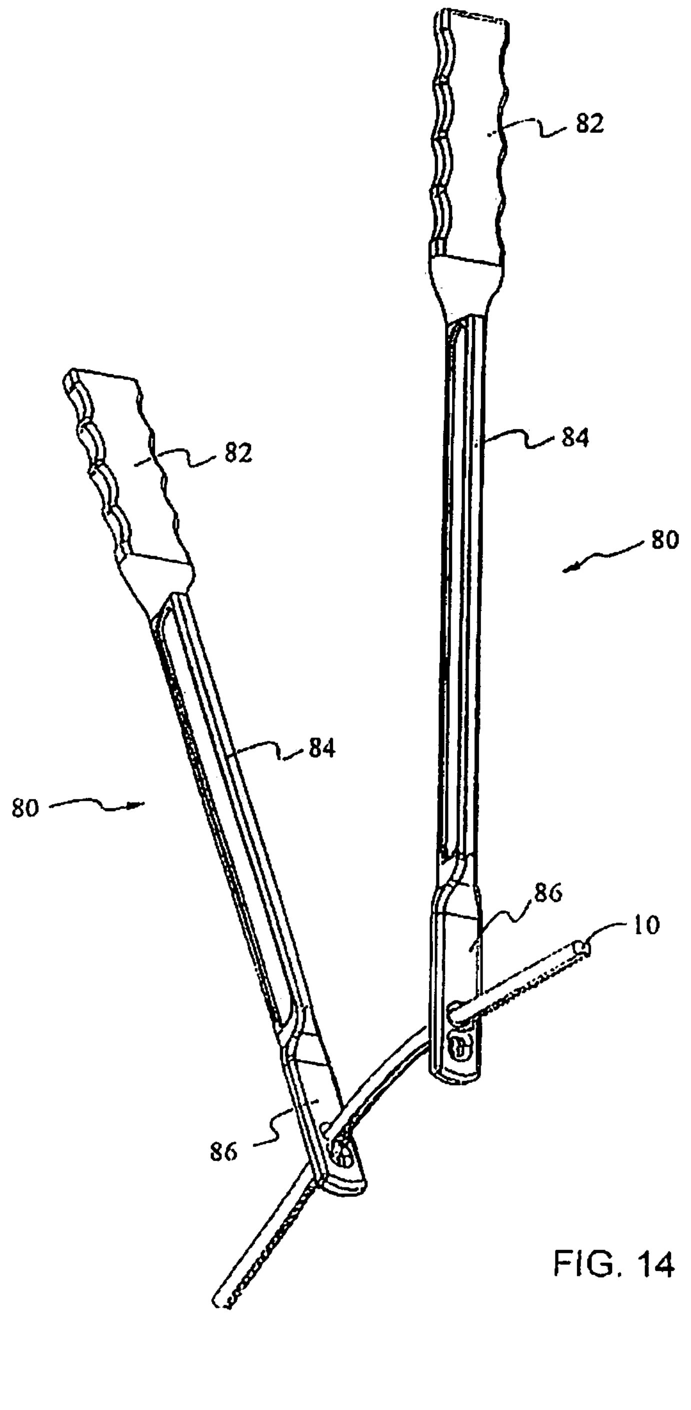


FIG. 14

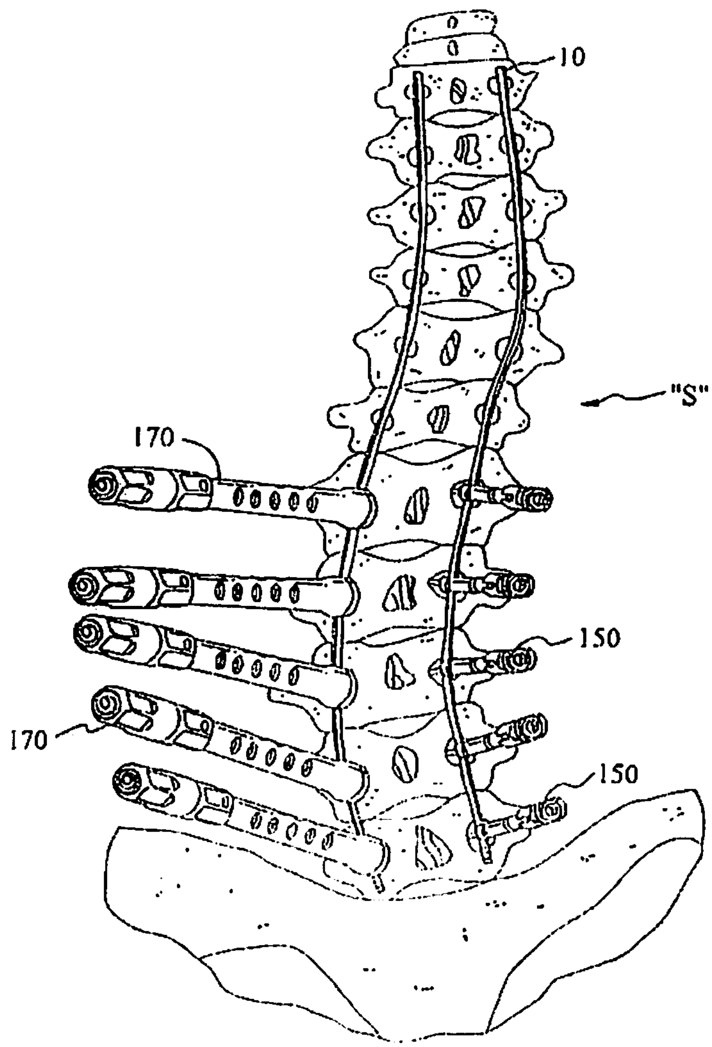
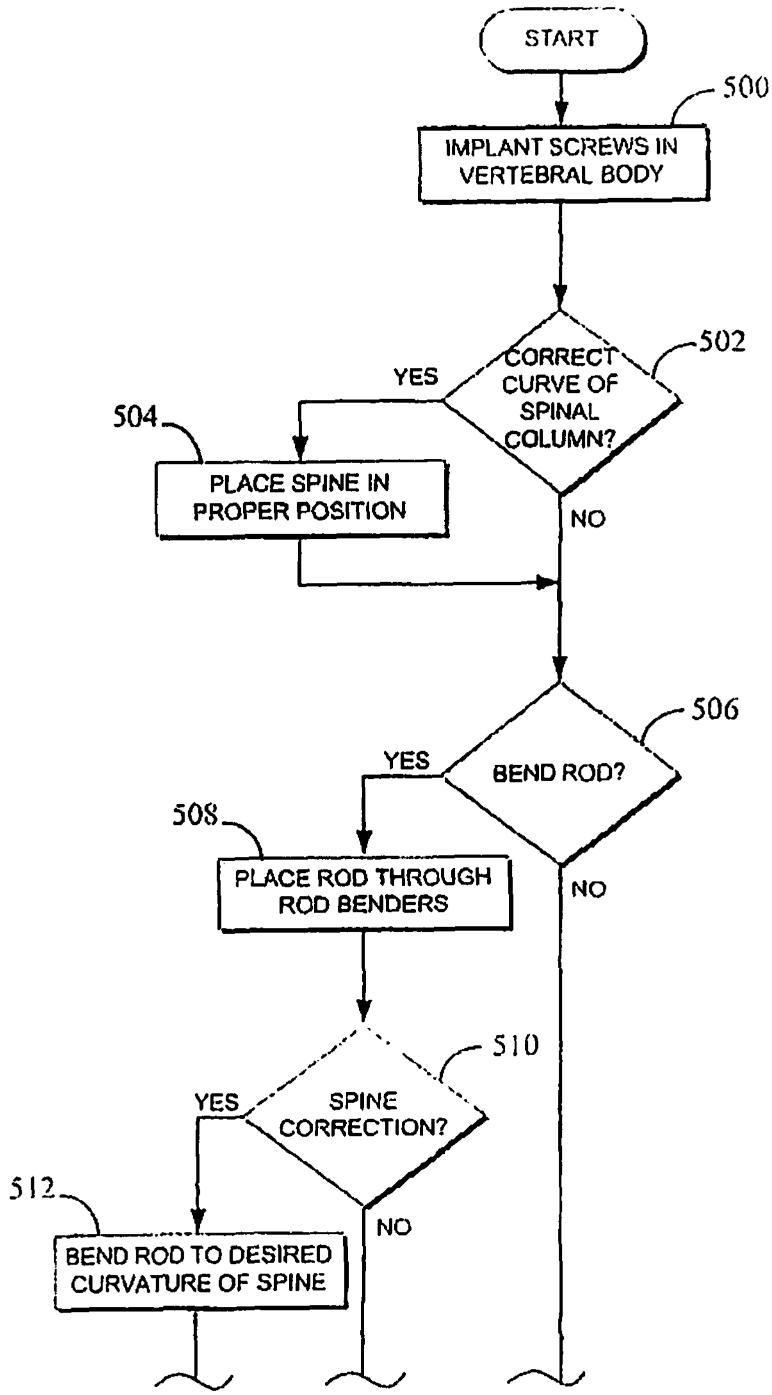


FIG. 15



START
500
IMPLANT SCREWS IN VERTEBRAL BODY
502
CORRECT CURVE OF SPINAL COLUMN?
YES
NO
504
PLACE SPINE IN PROPER POSITION
506
BEND ROD?
YES
NO
508
PLACE ROD THROUGH ROD BENDERS
510
SPINE CORRECTION?
YES
NO
512
BEND ROD TO DESIRED CURVATURE OF SPINE

FIG. 16A

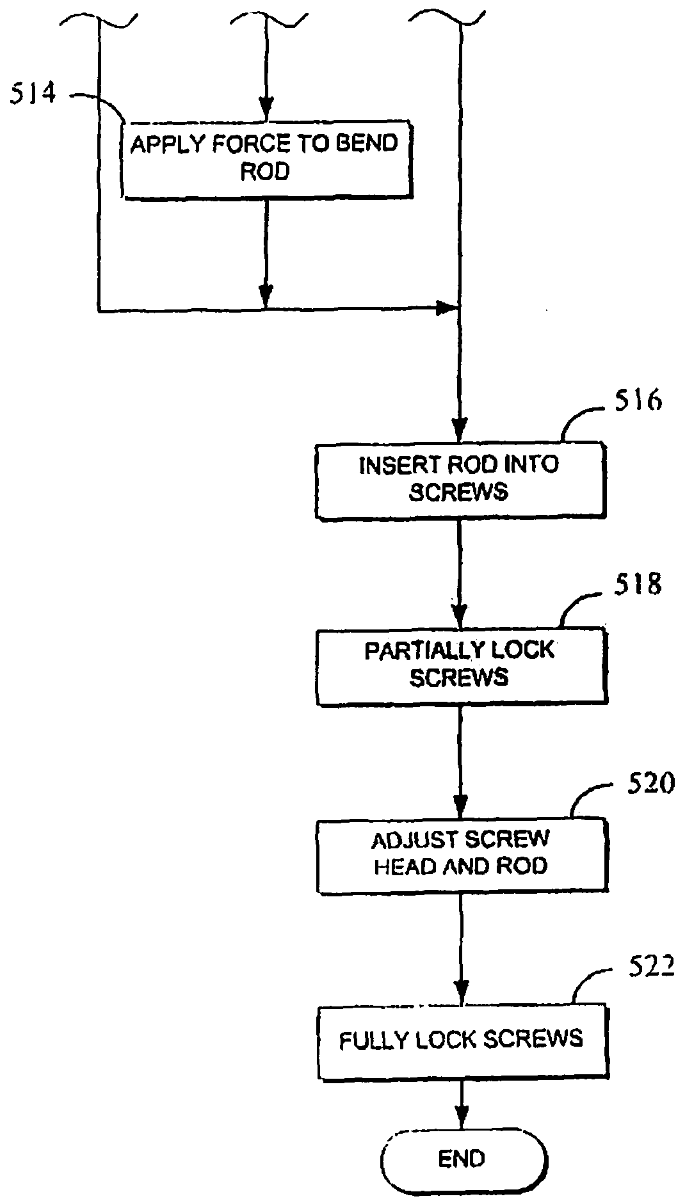

514
APPLY FORCE TO BEND ROD
516
INSERT ROD INTO SCREWS
518
PARTIALLY LOCK SCREWS
520
ADJUST SCREW HEAD AND ROD
522
FULLY LOCK SCREWS
END

FIG. 16B

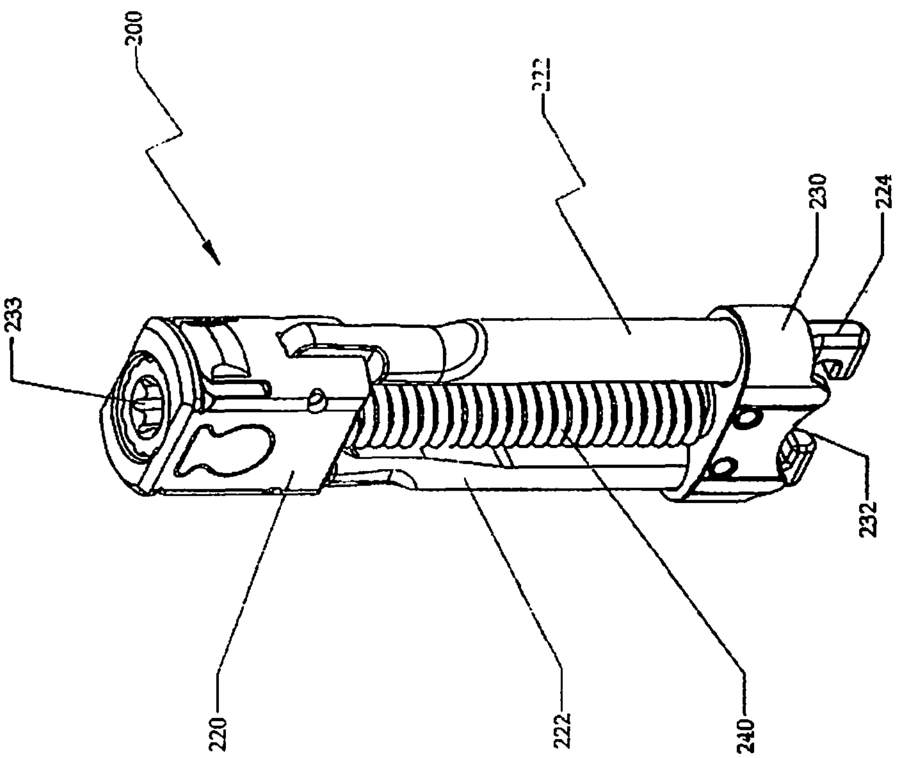


FIG. 17

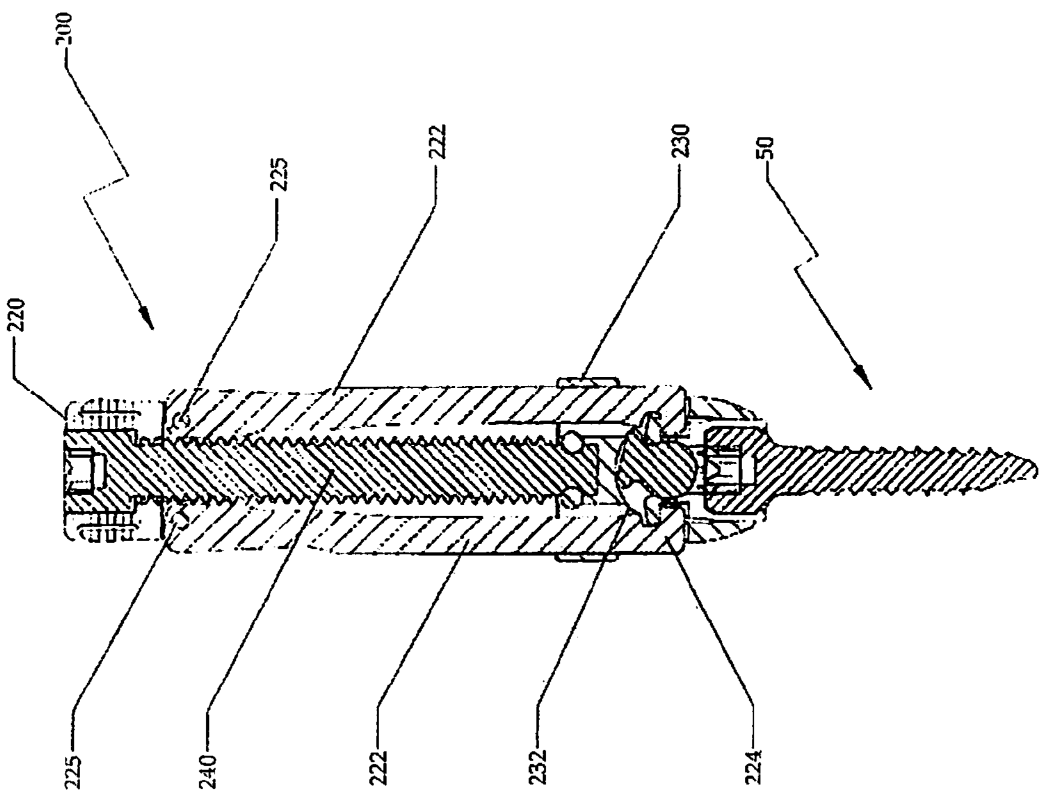


FIG. 17A

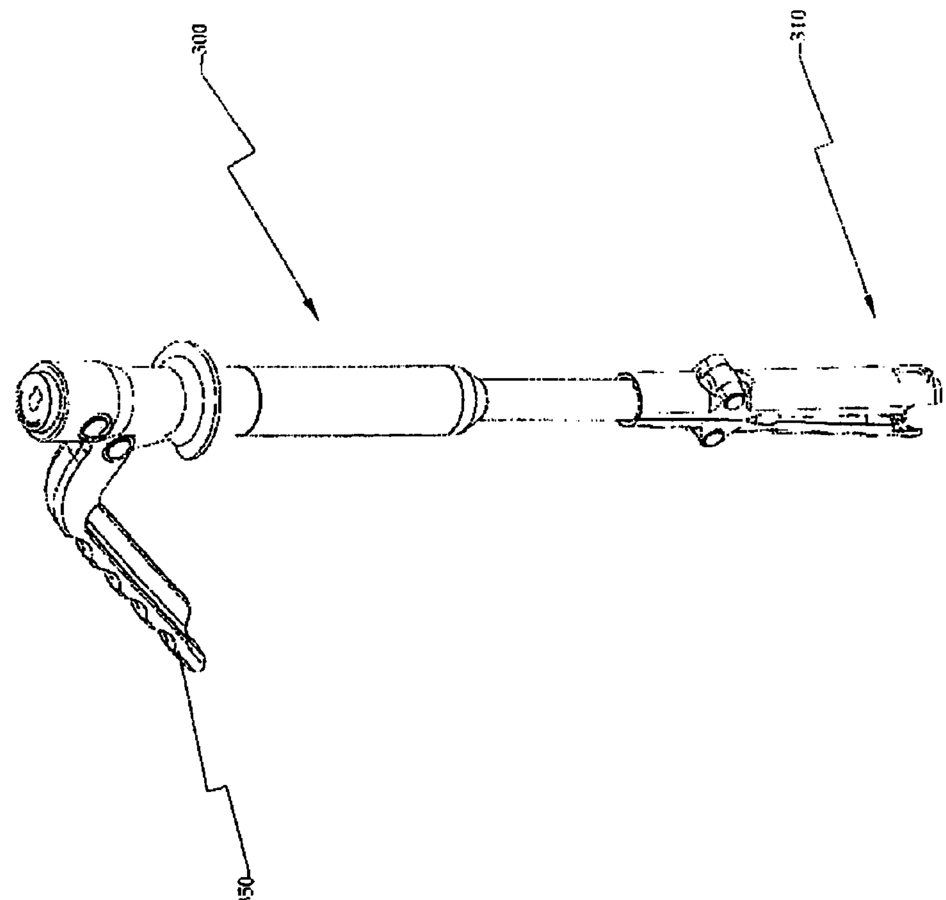


FIG. 18

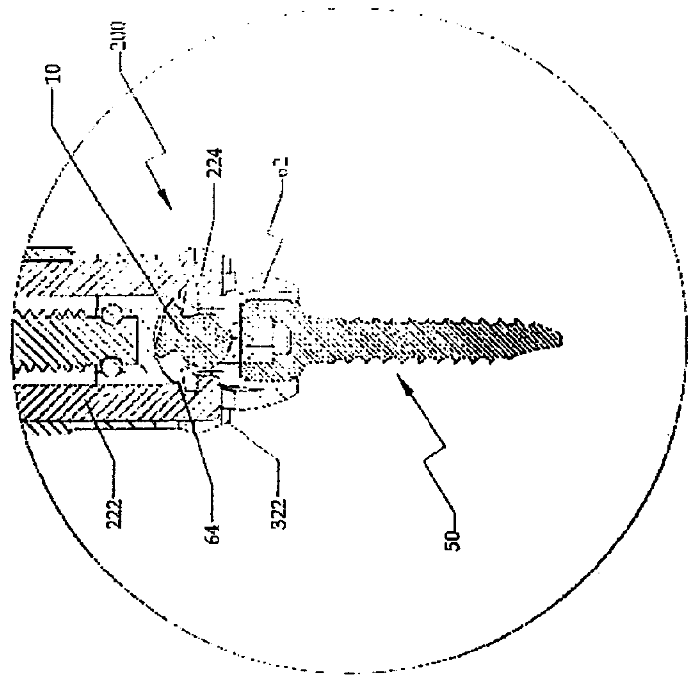


FIG. 18B

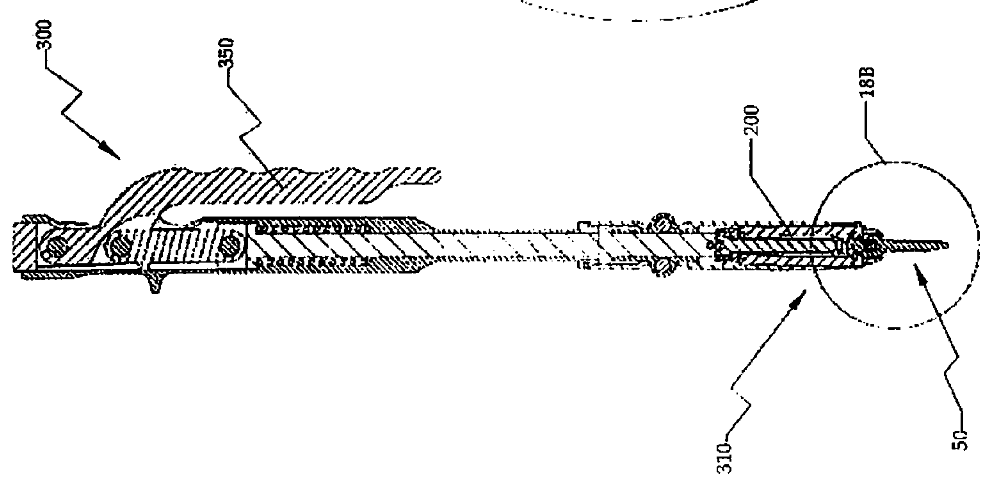


FIG. 18A

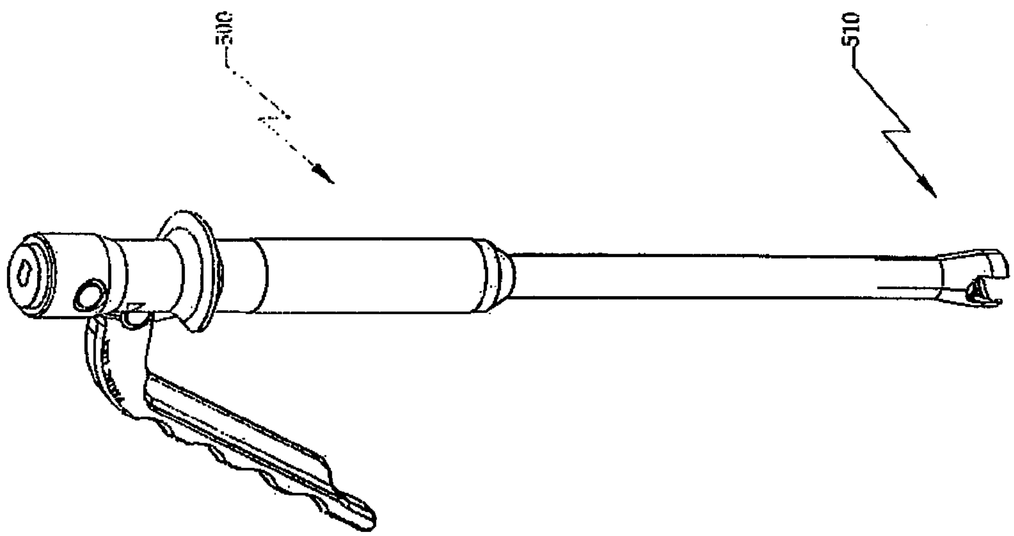


FIG. 19

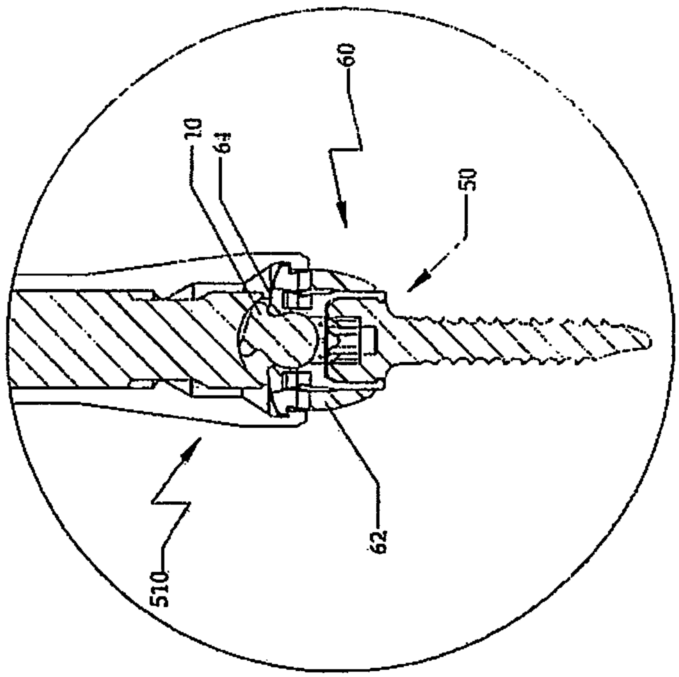


FIG. 19B

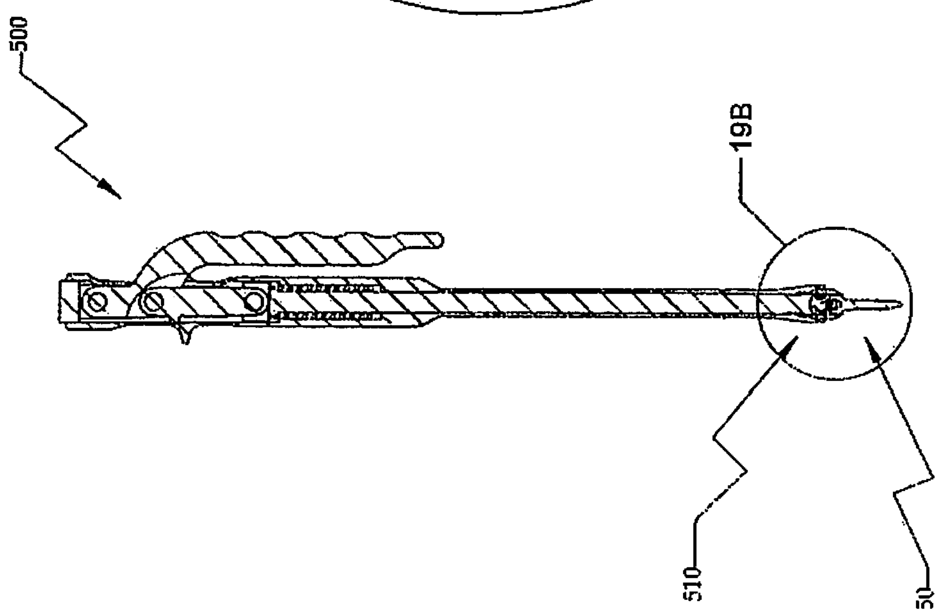


FIG. 19A

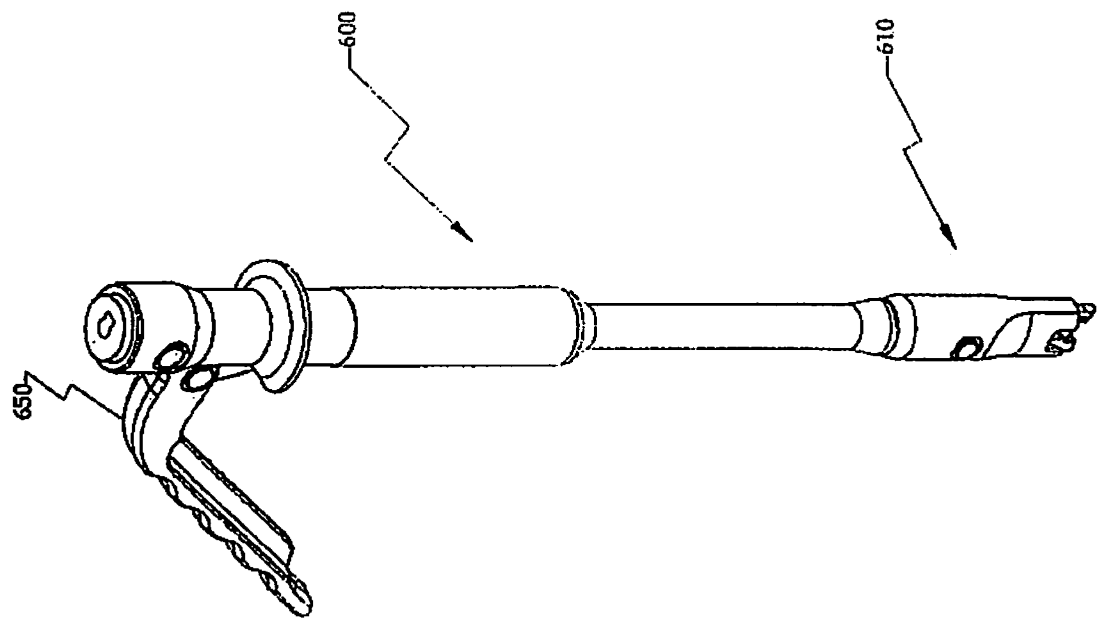


FIG. 20

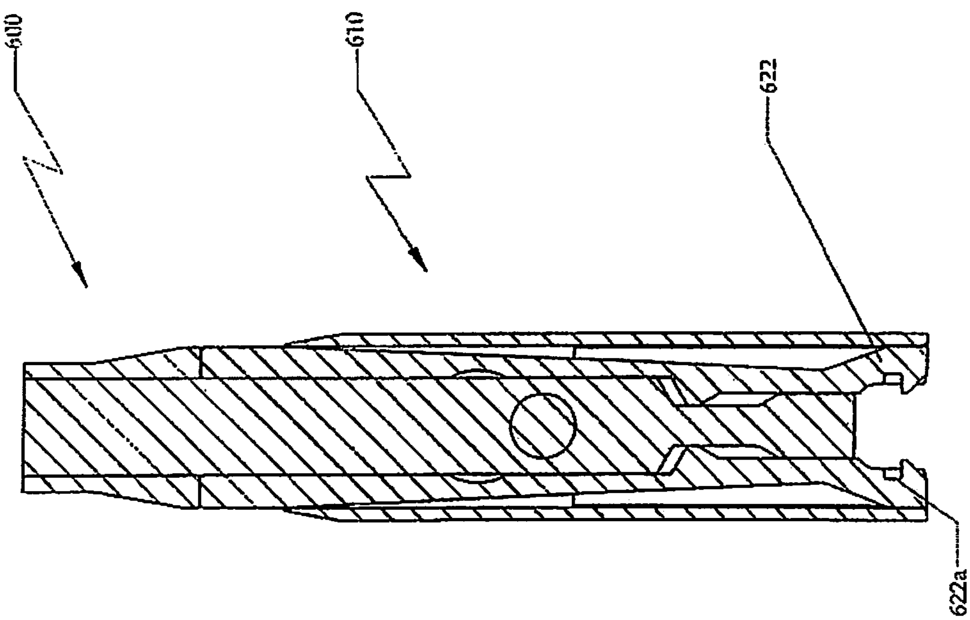


FIG. 20A

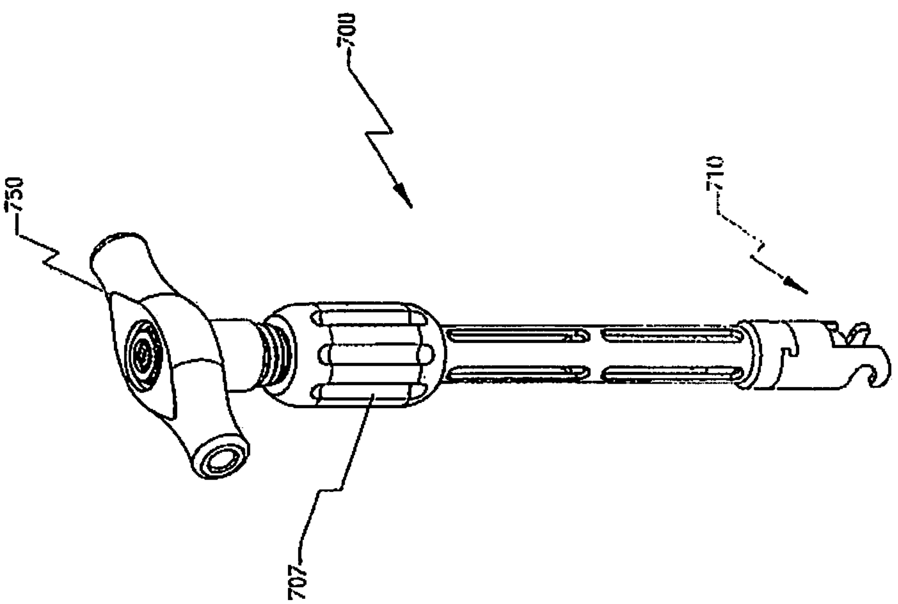


FIG. 21

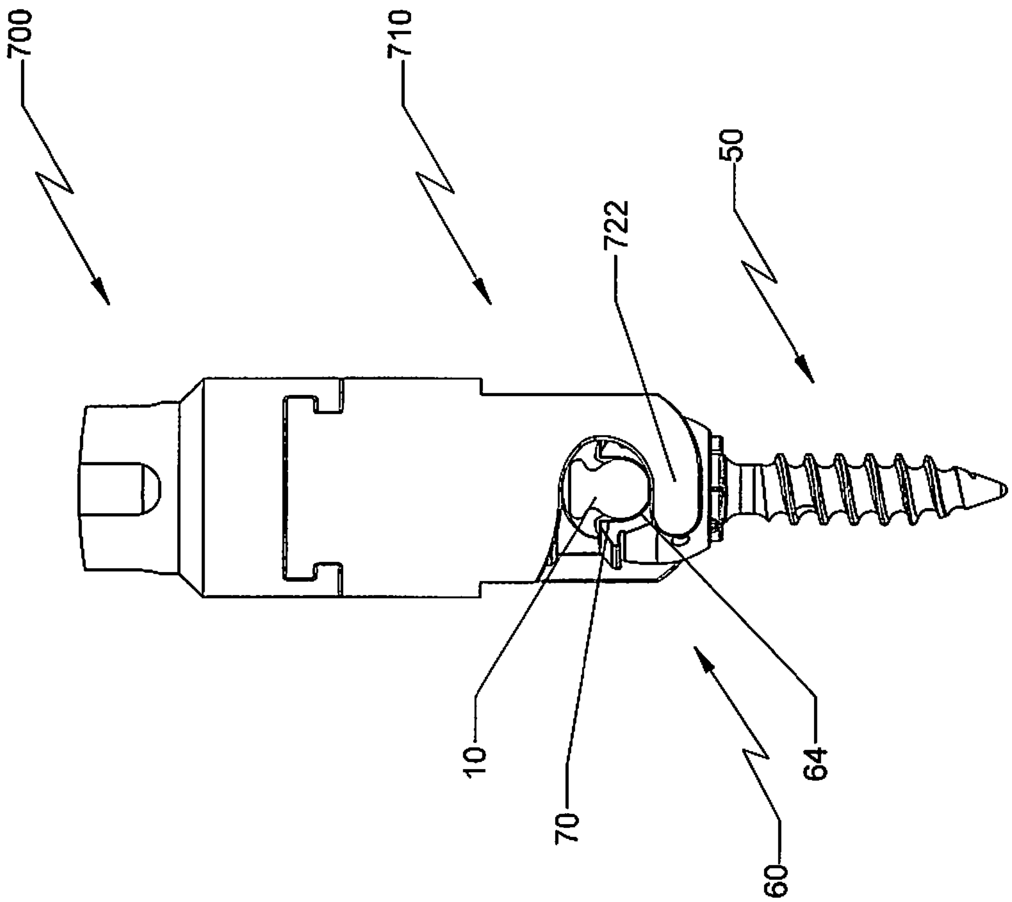


FIG. 21A

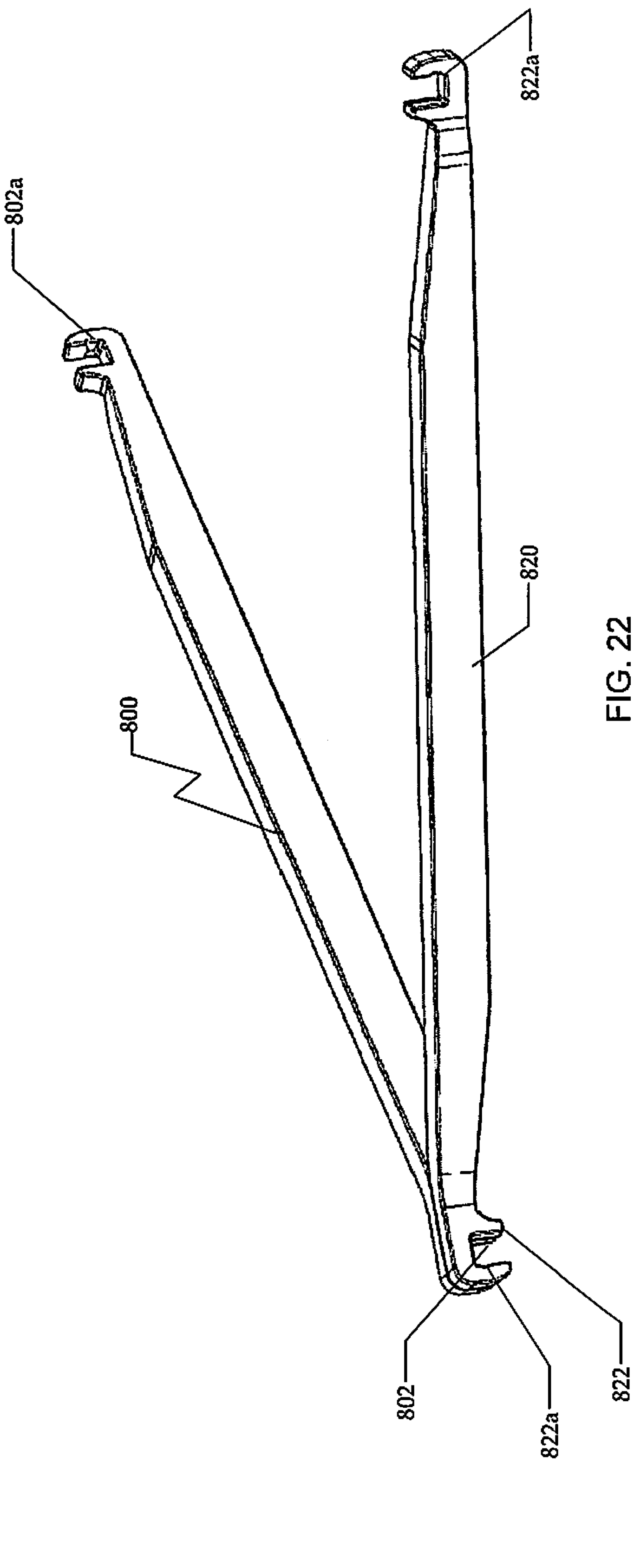


FIG. 22

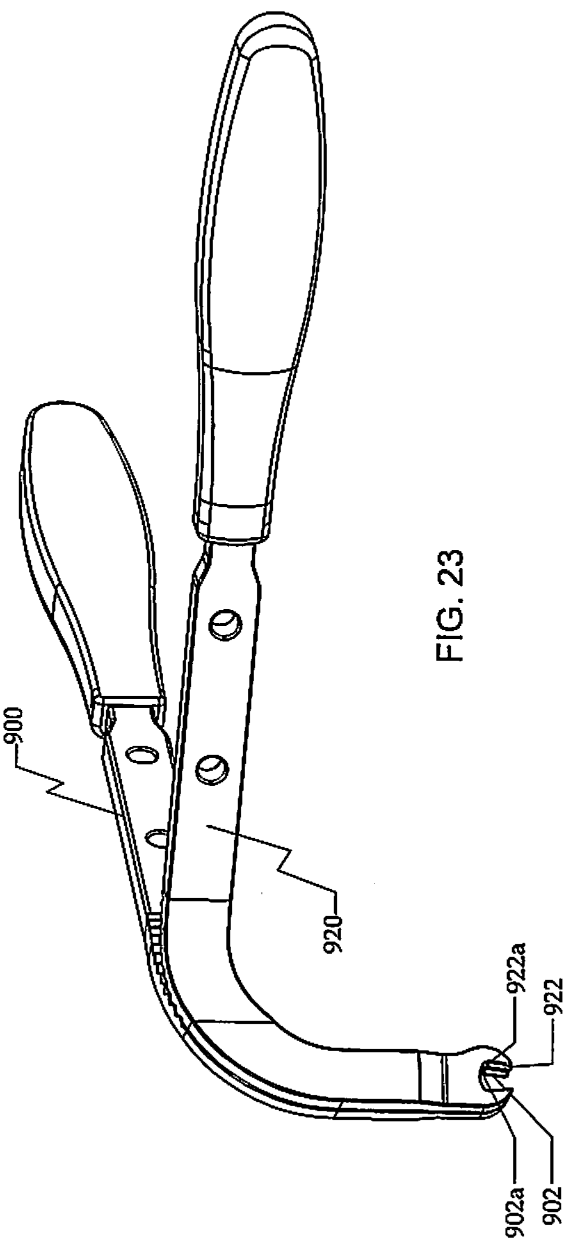


FIG. 23

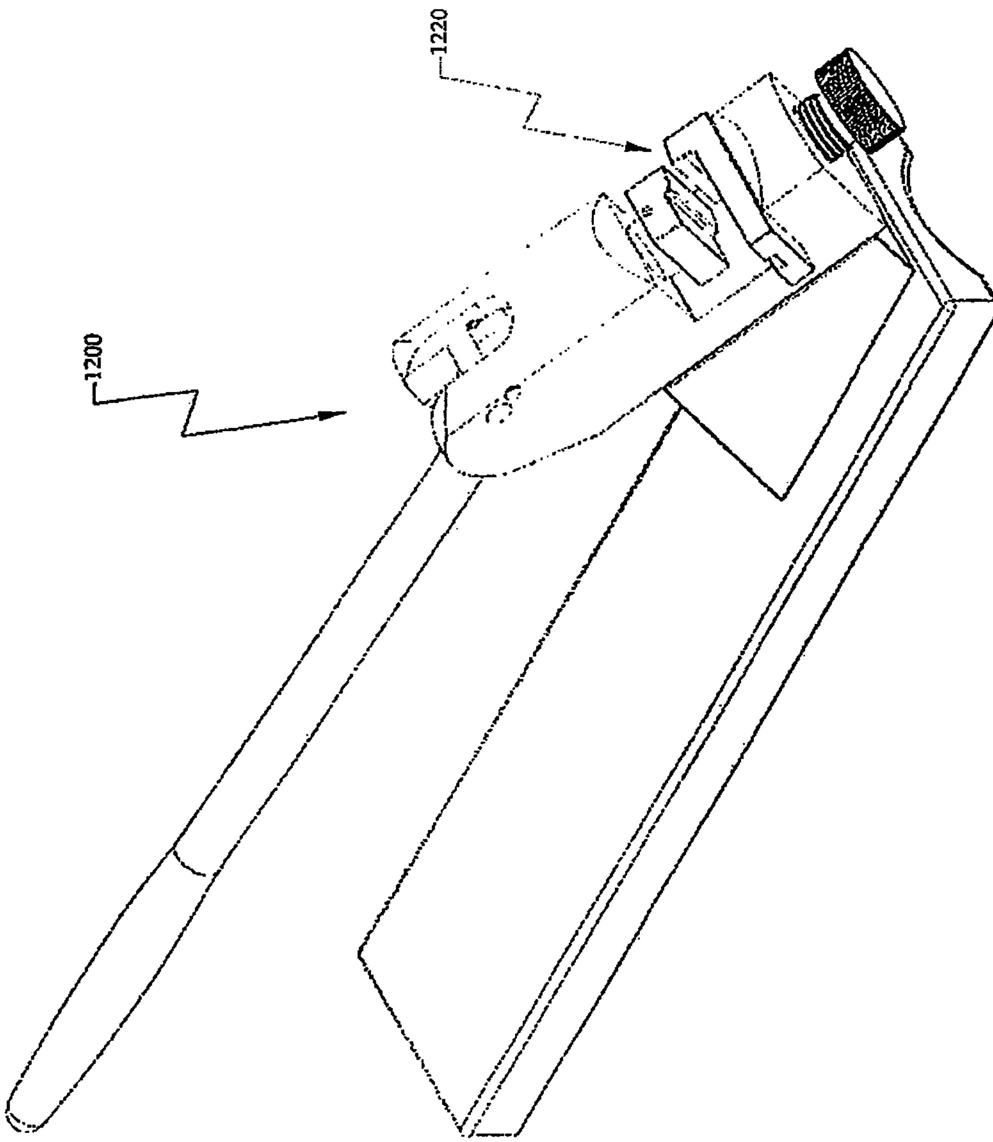


FIG. 24

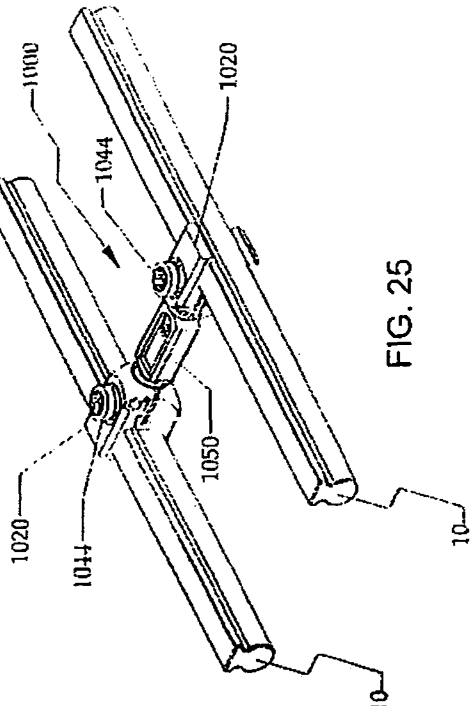


FIG. 25

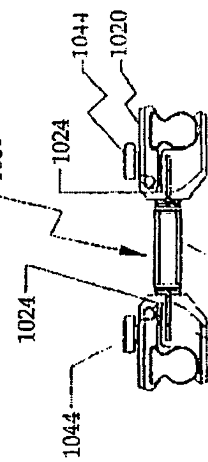


FIG. 28

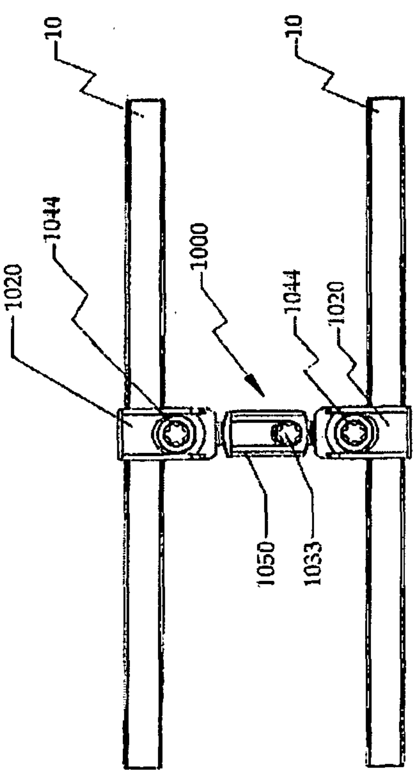


FIG. 26

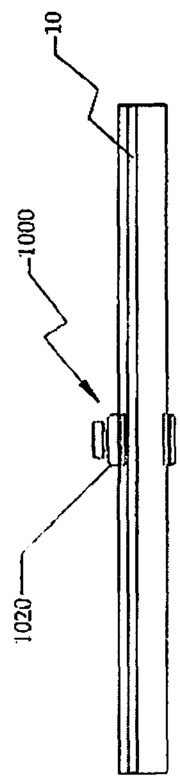


FIG. 27

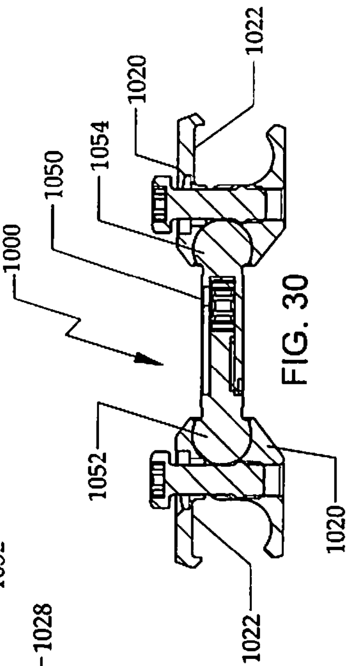


FIG. 30

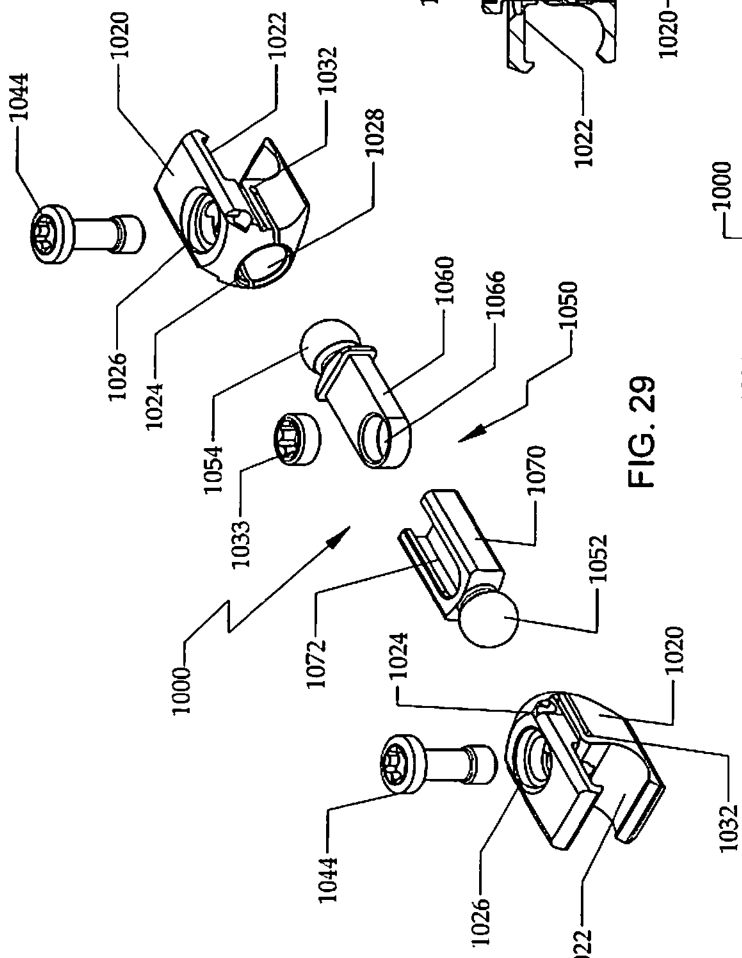


FIG. 29

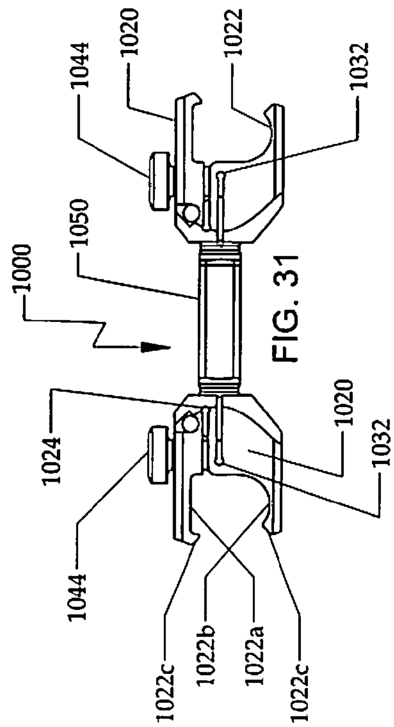


FIG. 31

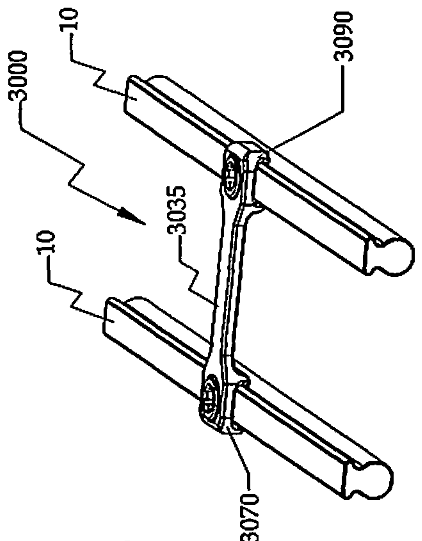

3000
10
10
3090
3035
3070

FIG. 33

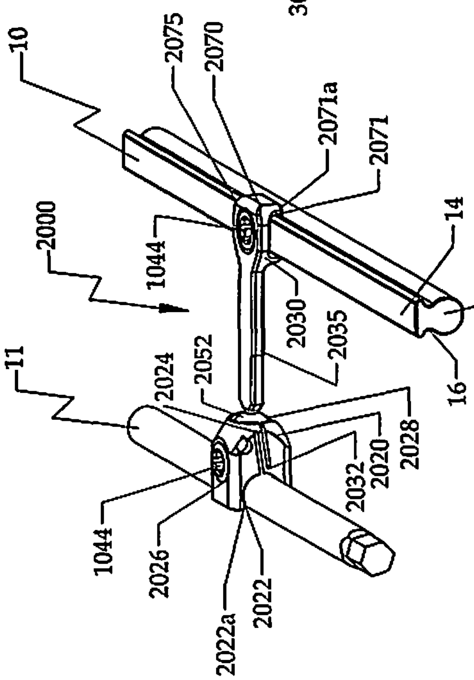

10
2075
2070
2071a
2071
2000
1044
14
12
16
2030
2035
11
2024
2052
2028
2020
2032
1044
2026
2022a
2022

FIG. 32

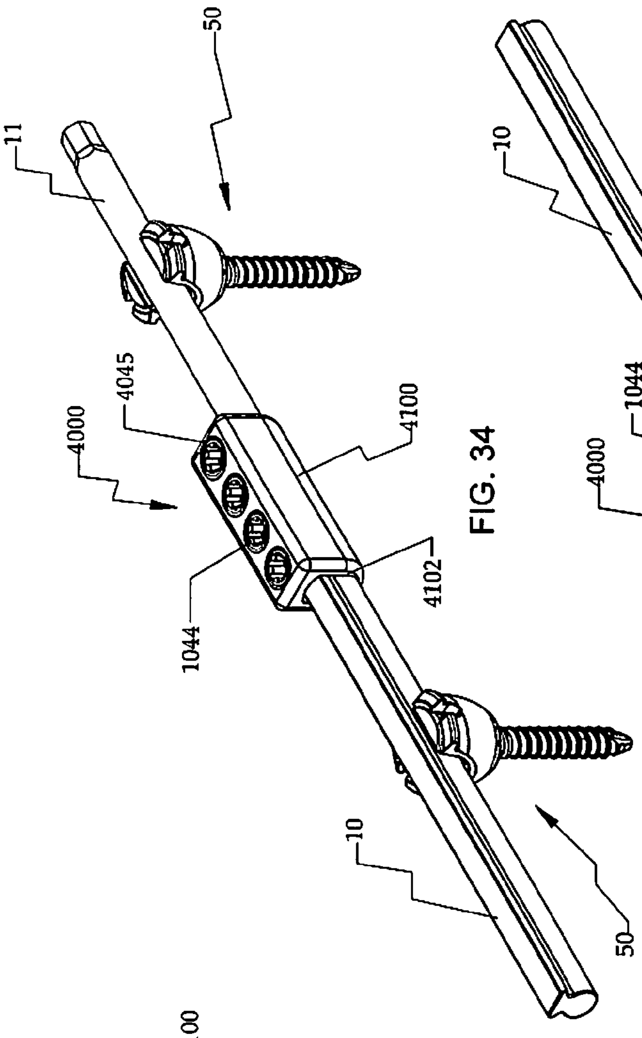


FIG. 34

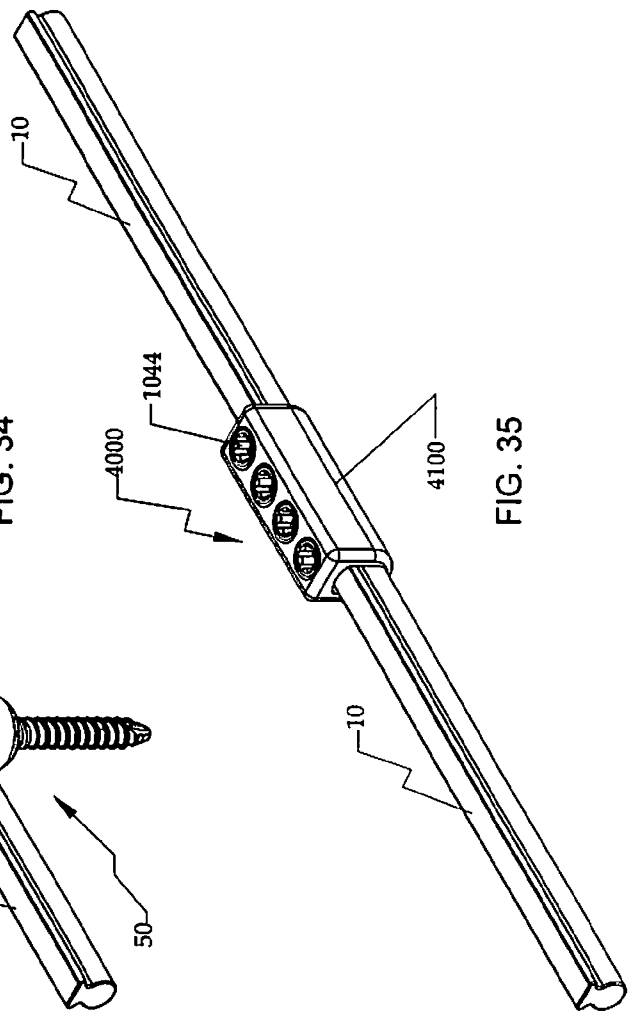


FIG. 35

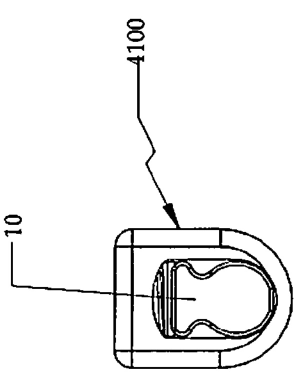


FIG. 34 A

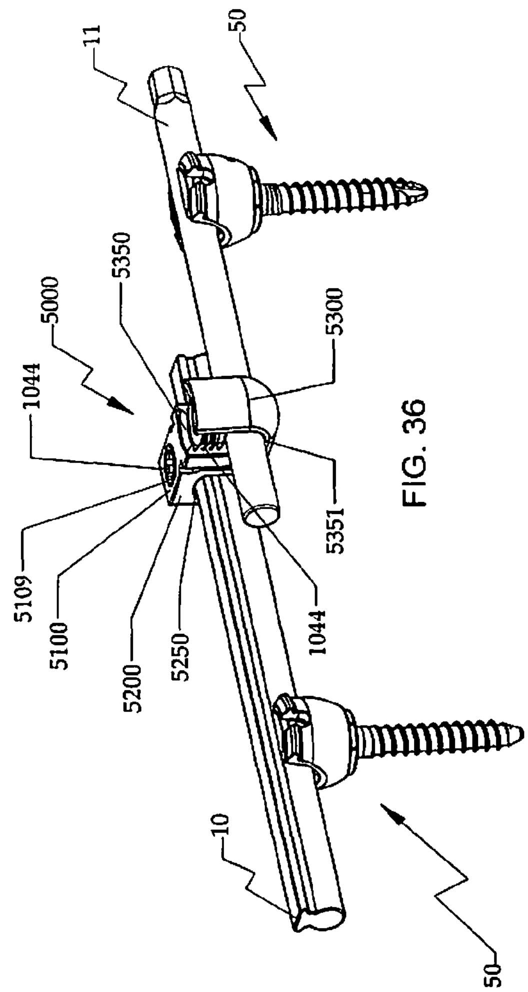


FIG. 36

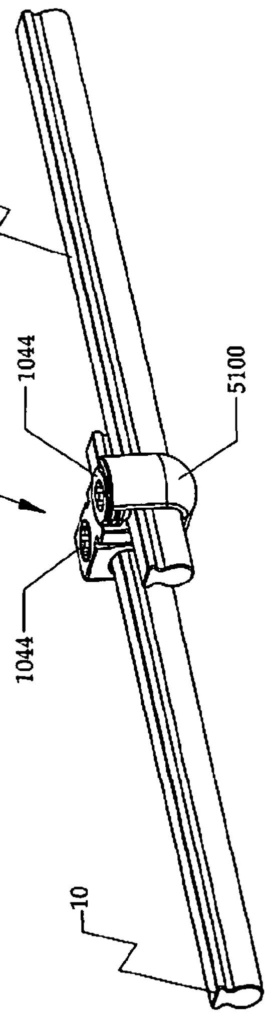


FIG. 37

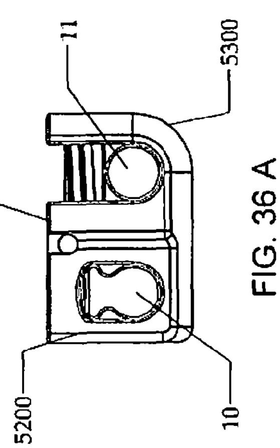


FIG. 36 A

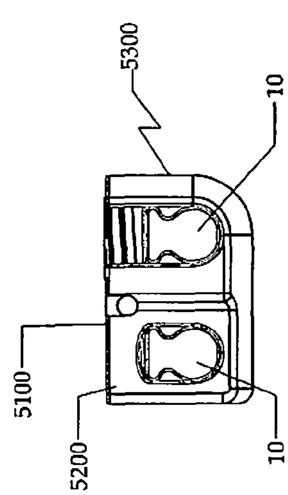


FIG. 37 A

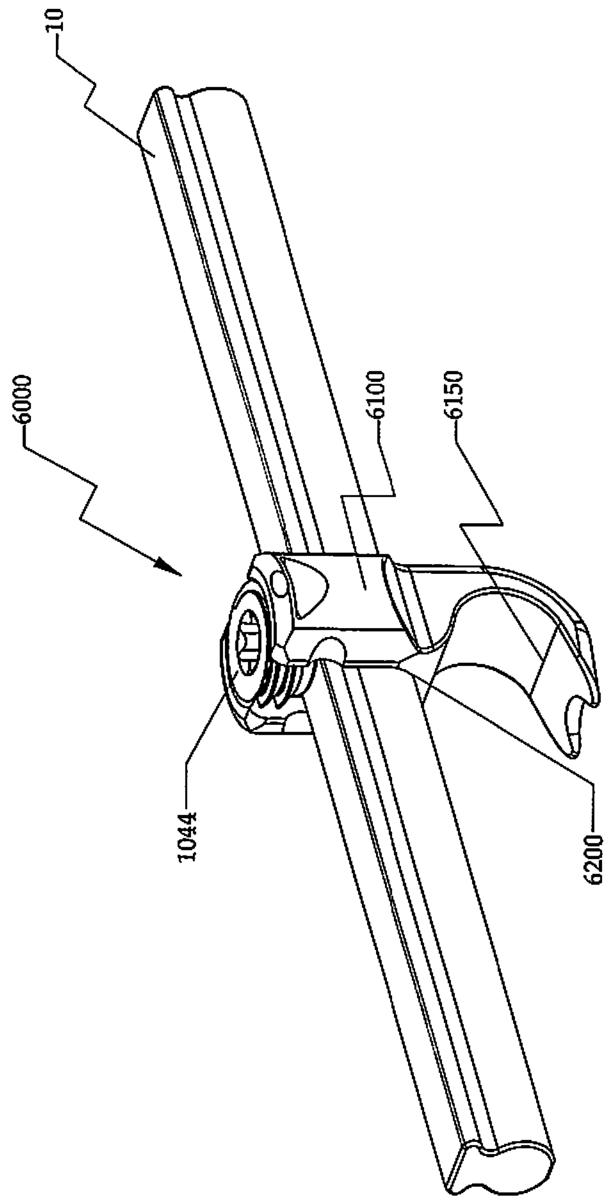


FIG. 38

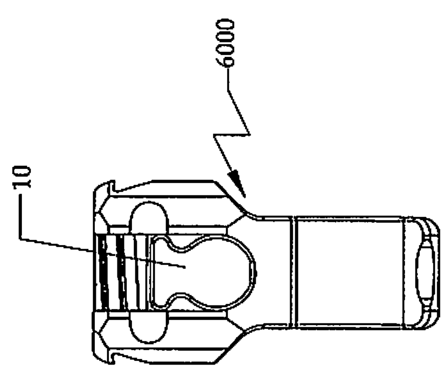


FIG. 38 A

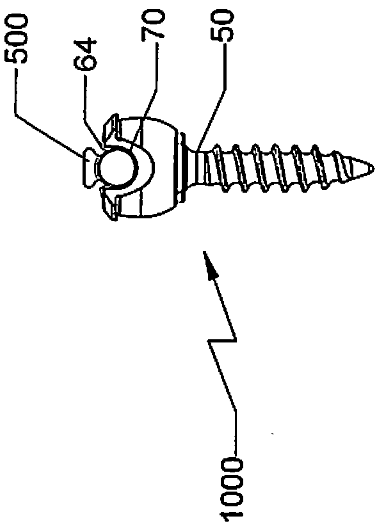

500
64
70
50
1000

FIG.40

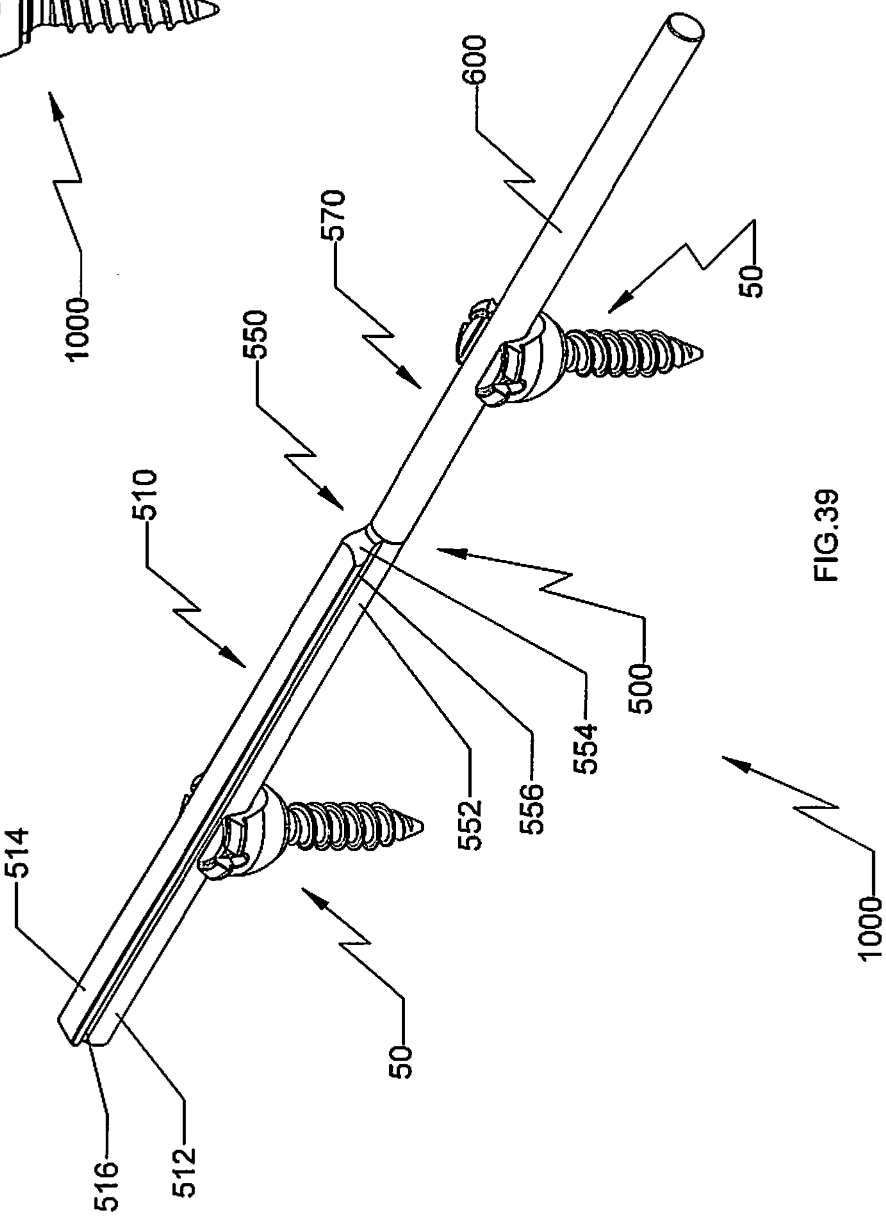

600
570
50
550
510
500
554
556
552
514
50
516
512
1000

FIG.39

SPINE STABILIZATION SYSTEM

CROSS-REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part of International Application No. PCT/US11/42127, filed on Jun. 28, 2011, which claims priority to, and the benefit of, U.S. Provisional Patent Application No. 61/359,028, filed on Jun. 28, 2010. The present application also claims priority to, and the benefit of, U.S. Provisional Patent Application No. 61/537,112, filed on Sep. 21, 2011. The entire contents of each of these prior applications are hereby incorporated by reference herein.

BACKGROUND

1. Technical Field

The present disclosure relates to orthopedic surgical devices, and more particularly, to a spinal stabilization system and a method of use therefor.

2. Background of Related Art

The spinal column is a complex system of bones and connective tissues that provide support for the human body and protection for the spinal cord and nerves. The adult spine is comprised of an upper and lower portion. The upper portion contains twenty-four discrete bones, which are subdivided into three areas including seven cervical vertebrae, twelve thoracic vertebrae and five lumbar vertebrae. The lower portion is comprised of the sacral and coccygeal bones. The cylindrical shaped bones, called vertebral bodies, progressively increase in size from the upper portion downwards to the lower portion.

An intervertebral disc along with two posterior facet joints cushion and dampen the various translational and rotational forces exerted upon the spinal column. The intervertebral disc is a spacer located between two vertebral bodies. The facets provide stability to the posterior portion of adjacent vertebrae. The spinal cord is housed in the canal of the vertebral bodies. It is protected posteriorly by the lamina. The lamina is a curved surface with three main protrusions. Two transverse processes extend laterally from the lamina, while the spinous process extends caudally and posteriorly. The vertebral bodies and lamina are connected by a bone bridge called the pedicle.

The spine is a flexible structure capable of a large range of motion. There are various disorders, diseases and types of injury, which restrict the range of motion of the spine or interfere with important elements of the nervous system. The problems include, but are not limited to, scoliosis, kyphosis, excessive lordosis, spondylolisthesis, slipped or ruptured discs, degenerative disc disease, vertebral body fracture, and tumors. Persons suffering from any of the above conditions typically experience extreme or debilitating pain and often times diminished nerve function. These conditions and their treatments can be further complicated if the patient is suffering from osteoporosis, or bone tissue thinning and loss of bone density.

Spinal fixation apparatuses are widely employed in surgical processes for correcting spinal injuries and diseases. When the disc has degenerated to the point of requiring removal, there are a variety of interbody implants that are utilized to take the place of the disc. These include interbody spacers, metal cages and cadaver and human bone implants. In order to facilitate stabilizing the spine and keeping the interbody in position, other implants are commonly employed, such as bone screws and rods. Depending on the pathology and treatment, a surgeon will select the appropriate spinal rod material and size, specifically, the cross-sectional diameter.

To meet the problem of providing a rigid pedicle screw and rod construct, especially for addressing the demands of stiff deformity corrections, larger rod constructs have been made to improve the strength of the screw and rod construct. Spinal rods are typically made of a titanium alloy. However when large deformity corrections need to be made, these rods are not always strong enough. Larger diameter stainless steel rods have been made for these applications, but a larger rod requires a larger mating screw head to contain the rod which in turn increases the profile of the construct. In addition, in order to reduce the likelihood of material incompatibility in vivo, the screw assembly also needs to be made of stainless steel to match the rod material, which is not a cost effective alternative.

Therefore, a need exists for a cost effective, rigid screw and rod construct that can still maintain a low profile, while maintaining the surgical correction.

SUMMARY

In accordance with an embodiment of the present disclosure, there is provided a spinal stabilization system including a connecting rod and a bone screw. The connecting rod includes an elongate round portion, an elongate head portion and a neck portion connecting the elongate round portion with the elongate head portion. The bone screw includes a housing portion and a screw shaft extending distally from the housing portion. The housing portion includes an inner housing and an outer housing slidably surrounding at least a portion of the inner housing. The inner housing defines a slot configured and dimensioned to releasably secure the elongate round portion of the connecting rod therein, wherein the outer housing is movable relative to the inner housing between an unlocked state in which the elongate round portion of the connecting rod is releasable from the slot defined in the inner housing and a locked state in which the connecting rod is secured in the slot.

The elongate head portion of the connecting rod may have a non-circular cross-section. In particular, the elongate head portion of the connecting rod may have a substantially rectangular cross-section. The neck portion of the connecting rod may have an arcuate profile. The neck portion and the elongate head portion of the connecting rod may be disposed proximal of the inner housing when the elongate round portion of the connecting rod is disposed in the slot defined in the inner housing. The connecting rod may be monolithically formed. The screw shaft may be fixed relative to the rod receiving portion, or may be coupled with the housing portion to permit uniaxial, monoaxial or polyaxial motion of the screw relative to the housing portion.

In accordance with another embodiment of the present disclosure, there is provided a spinal stabilization system including a connecting rod, a rod bending device, and a bone screw. The connecting rod includes an elongate round portion, an elongate head portion and a neck portion connecting the elongate round portion with the elongate head portion. The rod bending device includes an elongate body defining an aperture configured and dimensioned to receive therethrough the connecting rod in a single orientation. The bone screw includes a housing portion and a screw shaft extending distally from the housing portion. The housing portion includes an inner housing and an outer housing slidably surrounding at least a portion of the inner housing. The inner housing defines a slot configured and dimensioned to releasably secure the elongate round portion of the connecting rod therein, wherein the outer housing is movable relative to the inner housing between an unlocked state in which the elongate round portion of the connecting rod is releasable from the slot defined in the inner housing and a locked state in which the connecting rod is secured in the slot.

The rod bending device may further include a second aperture configured and dimensioned to receive the rod oriented orthogonal to the direction in which the first aperture receives the rod. Side walls defining the apertures may have an arcuate profile. The apertures may include a rounded portion and a non-circular portion. The non-circular portion of the apertures may have a substantially rectangular shape. The rod bending device may further include a third aperture configured and dimensioned to receive the rod oriented oppositely to the orientation in which the first aperture receives the rod.

In accordance with another aspect of the present disclosure, there is provided a method of stabilizing a spine. The method includes providing a spinal stabilization system including a connecting rod, a pair of rod bending devices, and a bone screw. In particular, the connecting rod includes an elongate round portion, an elongate head portion and a neck portion connecting the elongate round portion with the elongate head portion. The pair of rod bending devices each includes an elongate body defining at least one aperture therethrough, each aperture configured and dimensioned to receive therethrough the connecting rod in a single orientation. The bone screw includes a housing portion and a screw shaft extending distally from the housing portion. The housing portion includes an inner housing and an outer housing slidably surrounding at least a portion of the inner housing. The inner housing defines a slot configured and dimensioned to releasably secure the elongate round portion of the connecting rod therein, wherein the outer housing is movable relative to the inner housing between an unlocked state in which the elongate round portion of the connecting rod is releasable from the slot defined in the inner housing and a locked state in which the connecting rod is secured in the slot. The method further includes implanting a plurality of bone screws into a plurality of vertebral bodies, bending the connecting rod using the rod benders, inserting the connecting rod into the connecting rod slots in the plurality of bone screws, and locking the connecting rod in the connecting rod slots in the plurality of bone screws.

Bending the connecting rod may include inserting the connecting rod through an aperture in each of the pair of rod bending devices and applying leveraged force to the connecting rod through the handle members of the rod bending devices. Bending the connecting rod may include bending the connecting rod in an anterior-posterior orientation. Bending the connecting rod may include bending the connecting rod in a medial-lateral orientation. Providing multiple apertures in the rod bending devices facilitates bending the rod by permitting the rod to be oriented in various positions relative to the handles.

The pair of rod bending devices may include a plurality of apertures configured and dimensioned to receive therethrough the connecting rod. The plurality of apertures may be defined to receive the rod in different orientations. Bending the connecting rod may include inserting the connecting rod through the apertures of the pair of rod bending devices having different orientations and applying twisting force. In addition, inserting the connecting rod into the connecting rod slots in the bone screws may include positioning the elongate round portion of the connecting rod in the connecting rod slots in the plurality of bone screws. Bending the connecting rod may include bending the connecting rod to conform to a desired contour of the spine.

The method may further include orienting the plurality of bone screws to the contour of the connecting rod prior to locking the connecting rod in the connecting rod slots in the plurality of bone screws. In addition, locking the connecting rod in the connecting rod slots in the plurality of bone screws includes partially locking the connecting rod in the connecting rod slots.

In accordance with another aspect of the present disclosure, there is provided a kit for spinal surgery. The kit includes a connecting rod, a bone screw, a rod reduction device, a partial locker, and a quick locker. In particular, the connecting rod includes an elongate round portion, an elongate head portion and a neck portion connecting the elongate round portion with the elongate head portion. The bone screw includes a housing portion and a screw shaft extending distally from the housing portion. The housing portion includes an inner housing and an outer housing slidably surrounding at least a portion of the inner housing. The inner housing defines a slot configured and dimensioned to releasably secure the elongate round portion of the connecting rod therein, wherein the outer housing is movable relative to the inner housing between an unlocked state in which the elongate round portion of the connecting rod is releasable from the slot defined in the inner housing and a locked state in which the connecting rod is secured to the slot. The rod reduction device is configured and adapted for attachment to the housing portion of the bone screw to reduce the connecting rod into the slot defined in the inner housing. The partial locker is configured to move the outer housing relative to the inner housing to partially lock the connecting rod to the housing. The quick locker is configured to move the outer housing with respect to the connecting rod to fully lock the connecting rod to the housing.

In an embodiment, the partial locker may include a distal end portion configured and adapted to receive the reduction device while the reduction device remains operably engaged with the bone screw. In addition, the kit may further include an unlocker configured and adapted to move the outer housing of the bone screw relative to the inner housing and the connecting rod to fully unlock the connecting rod from the housing. The kit may also include a rod puller configured and adapted to selectively engage the connecting rod to enable the unseating of the connecting rod from within the slot of the inner housing of the bone screw.

In accordance with still another aspect of the present disclosure, there is provided a method of stabilizing a spine. The method includes providing a spinal stabilization system including a connecting rod, a bone screw, a rod reduction device, a partial locker, and a quick locker. In particular, the connecting rod includes an elongate round portion, an elongate head portion and a neck portion connecting the elongate round portion with the elongate head portion. The bone screw includes a housing portion and a screw shaft extending distally from the housing portion. The housing portion includes an inner housing and an outer housing slidably surrounding at least a portion of the inner housing. The inner housing defines a slot configured and dimensioned to releasably secure the elongate round portion of the connecting rod therein. The outer housing is movable relative to the inner housing between an unlocked state in which the elongate round portion of the connecting rod is releasable from the slot defined in the inner housing and a locked state in which the connecting rod is secured to the slot. The rod reduction device is configured and adapted for attachment to the housing portion of the bone screw to reduce the connecting rod into the slot defined in the inner housing. The partial locker is configured to move the outer housing relative to the inner housing to partially lock the connecting rod to the housing. The quick locker is configured to move the outer housing with respect to the connecting rod to fully lock the connecting rod to the housing. The method further includes implanting a plurality of bone screws into a plurality of vertebral bodies, inserting the elongated round portion of the connecting rod into the slots in the plurality of bone screws with the rod reduction device and locking the connecting rod in the slots in the plurality of bone screws.

In an embodiment, locking the connecting rod in the slots in the plurality of bone screws may include partially locking the connecting rod in the slots with the partial locker. In addition, locking the connecting rod in the slots in the plurality of bone screws may include fully locking the connecting rod in the slots with the quick locker.

In accordance with still yet another embodiment of the present disclosure, there is provided a spinal stabilization system including a pair of connecting rods and a cross connector assembly configured to couple the pair of connecting rods. Each connecting rod includes an elongate round portion, an elongate head portion and a neck portion connecting the elongate round portion with the elongate head portion. The cross connector assembly includes a pair of connectors each defining a recessed portion configured to secure one of the pair of connecting rods therein and an intermediate portion connecting the pair of connectors, wherein the recessed portion includes an arcuate wall configured to receive the elongate round portion of the connecting rod and an opposing non-circular wall configured to receive the elongate head portion of the connecting rod.

In an embodiment, each connector may define a slit configured to flex or enlarge the dimensions of the recessed portion to facilitate insertion of the connecting rod. The non-circular wall may have a substantially rectangular cross-section. The recessed portion may include a pair of opposing fingers to secure the connecting rod within the recessed portion. Furthermore, the intermediate portion may be retractable to enable adjustment of a length of the intermediate portion.

In another embodiment, the spinal stabilization system may further include a circular rod, wherein the arcuate wall of the recessed portion is configured to receive the circular rod therein.

In accordance with still yet another embodiment of the present disclosure, there is provided a spinal stabilization system including a pair of connecting rods and a cross-connector assembly configured to couple the pair of connecting rods. Each connecting rod includes an elongate round portion, an elongate head portion and a neck portion connecting the elongate round portion with the elongate head portion. The cross connector includes a pair of connectors each defining a recessed portion configured to secure one of the pair of connecting rods therein. The recessed portion is configured to receive the elongate head portion of the connecting rod. Each recessed portion defines a pair of fingers to secure the elongate head portion therebetween.

In an embodiment, the cross connector may be made of a relatively flexible material to provide a snap fit engagement with the elongate head portion.

In accordance with still yet another embodiment of the present disclosure, there is provided a spinal stabilization system including a connecting rod and a bone screw. The connecting rod includes a first portion and a second portion. The first portion includes an elongate round portion, an elongate head portion, and a neck portion connecting the elongate round portion with the elongate head portion. The second portion includes a circular rod. The circular rod is coupled to the elongate round portion. The bone screw includes a housing portion and a screw shaft extending distally from the housing portion. The housing portion includes an inner housing and an outer housing slidably surrounding at least a portion of the inner housing. The inner housing defines a slot configured and dimensioned to releasably secure the connecting rod therein, wherein the outer housing is movable relative to the inner housing between an unlocked state in which the connecting rod is releasable from the slot defined in the inner housing and a locked state in which connecting rod is secured to the slot.

In an embodiment, the connecting rod may further include a transition portion connecting the first and second portions. The transition portion may be longitudinally tapered. In particular, the transition portion may include a first end having a cross section substantially identical to a cross section of the first portion and a second end having a cross section substantially identical to the cross section of the second portion. In addition, the first end may be adjacent the first portion and the second end may be adjacent the second portion. In another embodiment, the connecting rod may be monolithically formed.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other features of the present disclosure will become apparent to one skilled in the art to which the present disclosure relates upon consideration of the following description of the disclosure with reference to the accompanying drawings, wherein:

FIG. **1** is a perspective view of a spinal stabilization system in accordance with an embodiment of the present disclosure;

FIG. **2** is an end view of the spinal stabilization system of FIG. **1**;

FIG. **3** is a top view of the spinal stabilization system of FIG. **1**;

FIG. **4** is a side view of the spinal stabilization system of FIG. **1**;

FIG. **5** is a partial cross-sectional view of a taper lock screw of the spinal stabilization system of FIG. **1** shown in an unlocked position to receive a rod;

FIG. **5**A is an end, cross-sectional view of the spinal stabilization system of FIG. **1** in a locked position;

FIG. **6** is a perspective view of a connecting rod of the spinal stabilization system of FIG. **1**;

FIG. **7** is an end view of the connecting rod of FIG. **6**;

FIG. **8** is a top view of the connecting rod of FIG. **6**;

FIG. **9** is a side view of the connecting rod of FIG. **6**;

FIG. **10** is a graph illustrating deflection of the connecting rod of FIG. **6**;

FIG. **11** is a graph illustrating flexural rigidity of the connecting rod of FIG. **6**;

FIG. **12**A is a side view of a rod bender device for use with the spinal stabilization system of FIG. **1**;

FIG. **12**B is a side cross-sectional view of the area of detail indicated in FIG. **12**A;

FIG. **13** is a perspective view of a pair of rod bender devices of FIG. **12**A having the connecting rod of FIG. **6** inserted therethrough;

FIG. **14** is a perspective view of the pair of rod bender devices of FIG. **13** having the connecting rod of FIG. **6** inserted therethrough in a different orientation;

FIG. **15** is a perspective view of a spinal correction procedure on a deformed spine utilizing the spine stabilization system of FIG. **1**;

FIGS. **16**A and **16**B are flow charts illustrating an overview of a method of stabilizing a spine;

FIG. **17** is a perspective view of a rod reduction device for use with the spinal stabilization system of FIG. **1**;

FIG. **17**A is a front, cross-sectional view of the rod reduction device of FIG. **17** operatively connected to a screw and a connecting rod;

FIG. **18** is a perspective view of a partial locker for use with the spinal stabilization system of FIG. **1**;

FIG. **18**A is a longitudinal cross-sectional view of the partial locker of FIG. **18** operatively connected to a screw and a connecting rod;

FIG. **18**B is a longitudinal cross-sectional view of the area of detail indicated in FIG. **18**A;

FIG. **19** is a perspective view of a quick locker for use with the spinal stabilization system of FIG. **1**;

FIG. **19**A is a longitudinal cross-sectional view of the quick locker of FIG. **19** operatively connected to a screw and a connecting rod;

FIG. **19**B is a longitudinal cross-sectional view of the area of detail indicated in FIG. **19**A operatively connected to a screw and a connecting rod;

FIG. **20** is a perspective view of an unlocker for use with the spinal stabilization system of FIG. **1**;

FIG. **20**A is a partial, longitudinal cross-sectional view of the unlocker of FIG. **20**;

FIG. **21** is a perspective view of a rod puller for use with the spinal stabilization system of FIG. **1**;

FIG. **21**A is a partial, side view of the rod puller of FIG. **21** operatively connected to a screw and a connecting rod;

FIGS. **22-24** are perspective views of various rod benders for use with the spinal stabilization system of FIG. **1**;

FIG. **25** is a perspective view of a cross connector assembly for use with the spinal stabilization system of FIG. **1**;

FIG. **26** is a top view of the cross connector assembly of FIG. **25**;

FIG. **27** is a side view of the cross connector assembly of FIG. **25**;

FIG. **28** is an end view of the cross connector assembly of FIG. **25**;

FIG. **29** is an exploded perspective view of the cross connector assembly of FIG. **25** with parts separated;

FIG. **30** is an end, cross-sectional view of the cross connector assembly of FIG. **25**;

FIG. **31** is an end view of the cross connector assembly of FIG. **25**;

FIGS. **32** and **33** are perspective views of other cross connector assemblies for use with the spinal stabilization system of FIG. **1**;

FIG. **34** is a perspective view of an axial connector illustrating use with different connecting rods;

FIG. **34**A is a side view of the axial connector of FIG. **34** operatively coupling different connecting rods;

FIG. **35** is a perspective view of the axial connector of FIG. **34** illustrating use with the connecting rods of FIG. **1**;

FIG. **36** is a perspective view of an offset connector illustrating use with different connecting rods;

FIG. **36**A is a side view of the offset connector of FIG. **36** operatively coupling different connecting rods;

FIG. **37** is a perspective view of the offset connector of FIG. **36** illustrating use with the connecting rods of FIG. **1**;

FIG. **37**A is a side view of the offset connector of FIG. **37** operatively coupling the connecting rods of FIG. **1**;

FIG. **38** is a perspective view of a spinal hook for use with the spinal stabilization system of FIG. **1**;

FIG. **38**A is a side view of the spinal hook of FIG. **38** operatively coupled with the connecting rod of FIG. **7**;

FIG. **39** is a perspective view of a spinal stabilization system in accordance with yet another embodiment of the present disclosure; and

FIG. **40** is an end view of the spinal stabilization system of FIG. **39**.

DETAILED DESCRIPTION OF EMBODIMENTS

Embodiments of the present disclosure will now be described in detail with reference to the drawings, in which like reference numerals designate identical or corresponding elements in each of the several views. As used herein, the term "distal," as is conventional, will refer to that portion of the instrument, apparatus, device or component thereof which is farther from the user while, the term "proximal," will refer to that portion of the instrument, apparatus, device or component thereof which is closer to the user. In addition, the term "cephalad" is used in this application to indicate a direction toward a patient's head, while the term "caudad" indicates a direction toward the patient's feet. Further still, for the purposes of this application, the term "medial" indicates a direction toward the middle of the body of the patient, while the term "lateral" indicates a direction toward a side of the body of the patient, i.e., away from the middle of the body of the patient. The term "posterior" indicates a direction toward the patient's back, while the term "anterior" indicates a direction toward the patient's front. In the following description, well-known functions or constructions are not described in detail to avoid obscuring the present disclosure in unnecessary detail.

With reference to FIGS. **1-4**, an embodiment of the present disclosure is shown generally as a spinal stabilization system **100**. Spinal stabilization system **100** includes at least one bone screw **50** and a connecting rod **10** releasably secured to bone screw **50**. Bone screw **50** is a multi-planar taper lock screw that enables manipulation of a screw shaft **52** about multiple axes, whereby bone screw **50** is capable of securing connecting rod **10** with bone screws **50** on multiple vertebral bodies that are aligned in the spinal column on different planes due to the natural curvature of the spine. However, it is also envisioned that bone screws **50** may be, for example, fixed angle screw, uniplanar screws or monoaxial taper lock screws.

One suitable taper lock screw is commercially available from K2M, Inc. (Leesburg, Va.) under the trade name MESA™. In addition, suitable multi-planar taper lock screws are shown and described in U.S. Patent Application Publication 2008/0027432 and in U.S. Patent Application Publication 2007/0093817, both of which are herein incorporated by reference in their entireties. It is contemplated that other types of screws such as, e.g., a fixed screw in which the head of the screw has no movement relative to the screw shaft, a mono-axial screw such as that disclosed in U.S. Patent Application Publication 2009/0105716, and a uni-axial screw such as that disclosed in U.S. Patent Application Publication 2009/0105769 may be utilized. Suitable mono-axial and uni-axial screws are also commercially available under the trade name MESA™.

With reference now to FIGS. **4**, **5** and **5**A, a suitable multi-planar taper lock bone screw **50** includes a dual layered housing **60** and screw shaft **52** having a spherically configured screw head **54** rotatably coupled with housing **60**. In particular, dual layered housing **60** includes an outer housing **62** and an inner housing **64**. Outer housing **62** can be selectively positioned relative to inner housing **64** to fully lock screw head **54** and connecting rod **10** in position within inner housing **64** (see FIG. **4**) or alternatively to selectively partially lock screw head **54** and/or connecting rod **10** in position while permitting a sliding and/or rotating motion of the connecting rod **10** relative to screw head **54**, and the screw head **54** relative to bone screw **50**, respectively. Specifically, outer housing **62** is configured such that at least a portion of an inner surface of outer housing **62** is capable of sliding over a portion of an outer surface of inner housing **64** in upward and downward directions along the longitudinal axis of bone screw **50**. When outer housing **62** is slid upward in relation to inner housing **64** an inner surface of outer housing **62** causes inner housing **64** to impart compressive force radially inward to secure connecting rod **10** at least partially disposed therein.

With continued reference to FIG. **5**, inner housing **64** defines a connecting rod slot **70** that is configured and dimensioned to accommodate the connecting rod geometry contemplated by the present disclosure, and to retain connecting rod **10** in inner housing **64** without impairing the locking ability of bone screw **50**. Specifically, an elongate rounded section **12** of connecting rod **10** is releasably secured in connecting rod slot **70** of inner housing **64**, as will be discussed in detail below. The term "rounded" in elongate rounded section **12** refers to a portion of connecting rod **10** having a generally circular/arcuate cross-section that is received in bone screw **50**. In particular, inner walls that define connecting rod slot **70** imparts compressive force to connecting rod **10** disposed in connecting rod slot **70**, whereby the inner walls serve to securely lock and hold connecting rod **10** in its relative position to inner housing **64**. This required forced is provided by the operational engagement of a locking device (not shown) with bone screw **50** that results in an upward sliding motion of outer housing **62** relative to inner housing **64**.

Inner housing **64** further defines a screw head articulation recess **66** in a lower portion of inner housing **64**. The interior surface of screw head articulation recess **66** has a complementary surface configuration to the generally spherical shape of screw head **54** to facilitate multi-planar rotational articulation of screw head **54** within articulation recess **66**. The lower-most portion of inner housing **64** defines a screw shaft exit portal **68** that is sized small enough to retain the spherical screw head **54** within screw head articulation recess **66**, but that is large enough to allow multi-directional movement of screw shaft **52** that extends exterior to inner housing **64**.

Outer housing **62** includes a receiving element configured to facilitate grasping of bone screw **50** by a locking and/or unlocking instrument (not shown) that can insert and lock connecting rod **10** securely into place in bone screw **50** or selectively unlock connecting rod **10** from bone screw **50** using complementarily designed unlocking instruments. The receiving element is a proximally located annular flange **74** radially extending from the upper portion of the outer surface of outer housing **62**.

With reference back to FIGS. **1-4**, connecting rod **10** is configured and dimensioned to be selectively and releasably secured to bone screw **50**. Connecting rod **10** is defined by an elongate body of a particular length. The elongate body is made of a biocompatible material such as Titanium (Ti-CP) and its alloys (e.g., Ti-6Al-4V), Cobalt-Chrome Alloy (CoCr) or Stainless Steel (SS).

With reference to FIGS. **6** and **7**, the elongate body of connecting rod **10** includes an elongate rounded section **12** having a substantially circular cross-section (see FIG. **7**), an elongate head portion **14**, and a neck portion **16** that connects and transitions elongate rounded section **12** into elongate head portion **14**, thereby providing reduced stress concentration along the elongate body of connecting rod **10**. Neck portion **16** has dimensions that are smaller than those of elongate rounded section **12** and elongate head portion **14**. The neck portion may define a pair of concave sides joining the elongate head portion to the elongate rounded portion, so that the concave sides provide clearance for the taper lock screw housings. The elongate body of connecting rod **10** may be monolithically formed as a unitary construct. For example, connecting rod **10** may be machined from a single piece of bar stock.

With reference now to FIGS. **6** to **9**, elongate head portion **14** may have a non-circular cross-section. As shown, elongate head portion **14** has a substantially rectangular cross-section having suitable dimensions of, for example, about 6 mm×about 1 mm (0.246 in.×0.039 in.). However, it is envisioned that elongate head portion **14** may have a cross-section that is substantially square, elliptical or any other shape to add rigidity to round section **12** of connecting rod **10**.

With particular reference back to FIGS. **5** and **6**, elongate rounded section **12** of connecting rod **10** is configured and dimensioned to be received in connecting rod slot **70** of inner housing **64** (see FIG. **2**). For example, round section **12** of connecting rod **10** may have a standard diameter of, for example, about 5.5 mm, suitable to mate with connecting rod slot **70**. Bone screw **50** may be positioned at any desired point along the elongate body of connecting rod **10**. When connecting rod **10** is secured to bone screw **50**, neck portion **16** of connecting rod **10** is disposed at the top of bone screw **50** (FIG. **2**) and does not interfere with the interaction between connecting rod **10** and bone screw **50**. Furthermore, elongate head portion **14** of connecting rod **10** is disposed above the top of taper lock screw **50**. While elongate head portion **14** is disposed above elongate rounded section **12**, head portion **14** does not appreciably increase the height profile of the screw-rod combination.

Connecting rod **10** affords greater strength and rigidity in comparison with ordinary circular rods with comparable dimensions. With reference now to FIG. **10**, connecting rods **10** made of different materials were placed under cantilever loading and were analyzed under Finite Element Analysis (FEA), wherein each rod sample was 100 mm in length. The distal end was fixed while the proximal end was subject to 200 N of force. Connecting rod **10** lacks radial symmetry. Accordingly, the graph differentiates deflection of connecting rod **10** between cantilever loading in flexion/extension and lateral bending.

For example, placing a circular rod formed from a titanium alloy (e.g. Ti-6Al-4V) under the same loading conditions as connecting rod **10** in FIG. **10** results in a deflection of about 13.4 mm for a rod diameter of 5.5 mm and a deflection of about 5.00 mm for a rod with a diameter of 7.00 mm. A stainless steel rod placed under the same loading conditions results in a deflection of about 8.00 mm for a rod diameter of 5.5 mm and a deflection of about 3.00 mm for a rod diameter of 7.00 mm. A rod formed from a cobalt chrome alloy under the same loading conditions has a deflection of about 6.8 mm for a rod diameter of 5.5 mm and a deflection of about 2.8 mm for a rod diameter of 7.00 mm.

Flexural rigidity of connecting rod **10** is shown in FIG. **11**. For example, circular rods made of a titanium alloy (e.g. Ti-6Al-4V) placed under the same loading conditions as connecting rod **10** in FIG. **11** have flexural rigidity of about 5.01 N-m^2 for a rod diameter of 5.5 mm and 23.5 N-m^2 for a rod diameter of 8.00 mm. Circular rods made of stainless steel placed under the same loading conditions have flexural rigidity of about 9.0 N-m^2 for a diameter of 5.5 mm and 40.01 N-m^2 for a rod diameter of 8.00 mm. Circular rods made of cobalt chrome alloy placed under the same loading conditions have flexural rigidity of about 10.1 N-m^2 for a rod diameter of 5.5 mm and 47.0 N-m^2 for a rod diameter of 8.00 mm.

Connecting rod **10** provides a greater stiffness and rigidity than circular rods having comparable dimensions in various materials. As such, connecting rod **10** and bone screw **50** construct affords greater rigidity and strength without increased bulk and profile. In addition, such construct, as shown, does not require any design changes to taper lock screw **50**, and thus advantageously provides efficiency of manufacture and inventory.

With reference now to FIGS. **12** to **14**, spinal stabilization system **100** may further include rod bender devices **80**. Each rod bender devices **80** define matching apertures **88** configured to receive and hold at least a portion of connecting rod **10** therein. Rod bender device **80** includes a handle member **82**, an elongate body **84** extending distally from handle portion **82**, and an engaging portion **86** coupled to elongate body **84**. Elongate body **84** is coupled or formed with handle member **82** and engaging portion **86** so as to reduce stress concentration. Handle member **82** may contain scalloped sections to facilitate gripping by the user. Elongate body **84** may have a rectangular cross-section and may define a cavity along the length thereof to reduce the weight of device. Engaging portion **86** defines at least one aperture **88** adapted and dimensioned to receive therethrough connecting rod **10**. In particular, inner walls that define aperture **88** are configured to permit insertion of connecting rod **10** through aperture **88** in a single orientation with respect to such aperture.

Aperture **88** has an arcuate end wall **88***a* configured to engage elongate rounded section **12** of connecting rod **10**, an opposite substantially straight end wall **88***b* configured to engage the substantially flat portion of elongate head portion **14** of connecting rod **10**, and connecting side walls **88***c* connecting arcuate end wall **88***a* and the substantially straight end wall **88***b*. In this manner, connecting rod **10** is inserted into each aperture **88** in a single orientation. Thus, in order to accommodate insertion of connecting rod in aperture **88** in various orientations, a plurality of apertures **88** is defined in engaging portion **86** in different orientations, as shown in FIG. **12**A-**12**B. For example, the pair of apertures **88** defined in engaging portion **86** is oriented at a 90-degree angle, whereby the rectangular portions of apertures **88** are substantially orthogonal to each other. In this manner, the user can bend connecting rod **10** in both an anterior-posterior orientation and a medial-lateral orientation. It is also contemplated that connecting rod **10** may be inserted in non-corresponding apertures **88** in rod bender devices **80** to facilitate twisting of connecting rod **10**, if necessary or desired.

The length of elongate body **84** is, for example, 18 inches. However, the length of elongate body **84** may be tailored to meet the needs of the surgical application to provide a suitable long moment arm necessary to provide the user a mechanical advantage to bend connecting rod **10**. In addition, it is also envisioned that elongate body **84** may be a hollow tubular member and/or define lightening holes to reduce the weight of device **80**.

With reference now to FIGS. **16**A and **16**B, a method of performing spinal stabilization utilizing spinal stabilization system **100** is illustrated. Initially, the user implants a plurality of bone screws **50** in vertebral bodies of a patient in step **500**. Preliminary to the operation of bone screw **50**, outer housing **62** is positioned in the open/unlocked position, that is, outer housing **62** is moved downward relative to inner housing **64**. Screw shaft **52** can then be driven into the desired vertebral body by providing torsional force via a driving tool (not shown) configured to mate with and grip bone screw **50**. After screw shaft **52** is positioned within the vertebral body and the driving tool removed from the screw, elongate rounded section **12** of connecting rod **10** can be positioned transversely within connecting rod slot **70** defined in inner housing **64**.

However, prior to securing connecting rod **10** with bone screw **50**, the surgeon can manipulate and correct the curve of the spinal column, i.e., to manually manipulate and reduce the "rib hump" in step **502**. After placing the spine in proper position in step **504**, the surgeon can bend connecting rod **10** in step **506** prior to securing connecting rod **10** to the first two points of the spinal column where the construct is to be attached.

The surgeon can bend connecting rod **10** by utilizing the pair of rod bender devices **80** in step **508**. In use, connecting rod **10** is inserted through selected apertures **88** of rod bender devices **80** and force is applied at handle members **82** of rod bender devices **80** to appropriately contour and shape connecting rod **10** to a desired curve in step **514**.

In particular, spinal stabilization system **10** can be utilized to correct spinal deformity (see FIG. **15**) in step **510** to appropriately contour and shape connecting rod **10** to a desired curvature of the spine, e.g., the sagittal curve, in step **512**.

For example, a rod reduction device or plurality of rod reduction devices **150** including a screw jack mechanism and a manipulation device or plurality of manipulation devices **170** adapted and configured for attachment to heads of taper lock bone screws **50**, and which provides leverage (i.e., long moment arm) to facilitate the manipulation of the spine may be utilized to orient the spine and place connecting rod **10** in bone screw **50**. In particular, rod reduction device **150** includes a housing with two arms that are pivotally attached to the housing, an anvil movably mounted on the two arms, and a screw threadably coupled with the housing and the anvil. The distal ends of arms provide positive and secure attachment of rod reduction device **150** with bone screw **50**. When the anvil is adjacent the housing the two arms are pivoted outwards, such that the distal ends of the arms can receive bone screw **50** therebetween. Rotating the screw of rod reduction device **150** in a first direction advances the screw through the housing and causes corresponding movement of the anvil toward bone screw **50**, which in turn causes the arms to move toward each other and provides positive engagement with bone screw **50**. The anvil defines an arcuately defined recess that is configured and dimensioned for positively engaging connecting rod **10**. The recess cooperates with connecting rod slot **70** and defines an opening adapted for receiving connecting rod **10**. With connecting rod **10** positioned in or near connecting rod slot **70**, the surgeon continues to advance the screw capturing connecting rod **10** between the recess of the anvil and connecting rod slot **70**. When the anvil is sufficiently advanced, the recess presses upon the outer surface of connecting rod **10** and pushes it into connecting rod slot **70**. A suitable rod reduction device **150** is disclosed in a commonly assigned U.S. Patent Application Publication No. 2009/0018593, the complete disclosure of which is fully incorporated herein by reference.

With reference to FIG. **15**, rod reduction device **150** is attached to the heads of bone screws **50** on the concave side of the spinal deformity. Manipulation device **170** is placed on bone screws **50** on the convex side of the spinal deformity. Depending on the nature of the deformity, however, rod reduction device **150** may be used on both sides of the deformity.

At this time, connecting rod **10** is positioned in slots **70** of bone screws **50** implanted in vertebral bodies in step **516**. With screw shaft **52** and screw head **54** being fixed in position relative to the vertebral body, bone screws **50** may be partially locked in step **518**. In particular, inner housing **64** and the circumferentially disposed outer housing **62** can be articulated relative to screw head **54** as necessary to manipulate the disposition of connecting rod **10** within bone screw **50** to make necessary adjustments in step **520**. For example, bone screw **50** may be partially locked to connecting rod **10** for compression, distraction and rotation without torsional stress being applied to the spine.

Upon completion of the necessary positional adjustments of inner housing recess **66** relative to screw head **54** and the adjustments of connecting rod **10** relative to connecting rod slot **70**, outer housing **62** can be grasped by the operator using the complementarily configured locking device. Activation of the locking device slides the outer housing upward circumferentially over the outer surface of inner housing **64** while the push rod holds down connecting rod **10** and inner housing **64** so that bone screw **50** is reconfigured from the open or unlocked position to closed or locked position in step **522**. Similarly, the operator can use the complementarily configured unlocking device to grasp inner housing **64** and slidably move outer housing **62** downward along the outer surface of inner housing **64** from a closed or locked position to an open or unlocked position. The rod and bone screw combination of the present disclosure may provide particular advantages in scoliosis or other spinal deformity surgery in which high stress levels are exerted upon such constructs at particular levels in the construct or over the entire length of such a construct.

With reference to FIGS. **17** and **17**A, spinal stabilization system **100** may further include a rod reduction device **200** configured and adapted for attachment to housing **60** of taper lock bone screws **50**. In particular, rod reduction device **200** includes a housing **220** with two arms **222** that are pivotally attached to housing **220**, an anvil **230** movably mounted on two arms **222**, and a screw **240** threadably coupled with housing **220** and anvil **230**. In particular, each arm **222** pivots about a pivot pin **225** disposed in housing **220**, whereby each arm **222** pivots relative to housing **220**. Distal ends **224** of arms **222** provide positive and secure attachment of rod reduction device **200** with bone screw **50**. When anvil **230** is adjacent housing **220**, two arms **222** are pivoted outwards, such that distal ends **224** of arms **222** can receive bone screw **50** therebetween. Screw **240** may be rotated using a tool (not shown) that engages a recess **233** in screw **240**. Rotating screw **240** of rod reduction device **200** in a first direction advances screw **240** through housing **220** and causes corresponding movement of anvil **230** toward bone screw **50**, which in turn causes arms **222** to move toward each other and provides positive engagement with bone screw **50**.

Anvil **230** has an arcuately defined recess **232** that is configured and dimensioned for positively engaging connecting rod **10**. The arcuate shape of recess **232** accommodates, i.e., drives, connecting rod **10** into bone screw **50**, independent of the orientation of connecting rod **10**. Recess **232** cooperates with connecting rod slot **70** and defines an opening adapted for receiving connecting rod **10**. With connecting rod **10** positioned in or near connecting rod slot **70**, the surgeon continues to advance screw **240** capturing connecting rod **10** between recess **232** of anvil **230** and connecting rod slot **70**. When anvil **230** is sufficiently advanced, recess **232** presses upon the outer surface of connecting rod **10** and urges it into connecting rod slot **70**.

With reference to FIGS. **18**-**18**B, spinal stabilization system **100** may also include a partial locker **300**. Partial locker **300** includes a distal end portion **310** configured to be received about reduction device **200** while reduction device **200** remains operably engaged with inner housing **64** of bone screw **50**. In particular, distal end portion **310** of partial locker **300** includes a plurality of graspers **322** configured to engage outer housing **62** of bone screw **50**. In particular, the plurality of graspers **322** are coupled operatively with a handle member **350**. When handle member **350** is in an unactuated position, as shown in FIG. **18**, the plurality of graspers **322** extend radially outward, and when handle member **350** is in an actuated position, as shown in FIGS. **18**A and **18**B, the plurality of graspers **322** move radially inward to engage outer housing **62** and to move outer housing **62** relative to inner housing **64** to partially lock connecting rod **10** to dual layered housing **60**. A suitable partial locker is disclosed in commonly assigned U.S. Patent Application Publication Nos. 2009-0018593 and 2007-0093817, the complete disclosures of which are fully incorporated herein by reference.

With reference now to FIGS. **19**-**19**B, spinal stabilization system **100** may further include a quick locker **500** including a distal end portion **510** that is configured to operably engage outer housing **62** of bone screw **50** and connecting rod **10**. In particular, quick locker **500** is used after reduction device **200** has been disengaged from dual layered housing **60** of bone screw **50**. Distal end portion **510** is configured to move outer housing **62** with respect to connecting rod **10** to fully lock connecting rod **10** to dual layered housing **60**. Optionally, connecting rod **10** may be partially locked with dual layered housing **60**.

With reference now to FIGS. **20**-**21**A, an unlocker **600** and a rod puller **700** may also be provided as part of spinal stabilization system **100**. Unlocker **600** includes a distal end portion **610** having a pair of arm members **622** coupled operatively to a lever **650**. Each arm member **622** includes a grasper **622***a*. The pair of graspers **622***a* are configured and adapted to engage outer housing **62** of bone screw **50** to move outer housing **62** relative to inner housing **64** and connecting rod **10** to fully unlock connecting rod **10** from dual layered housing **60**. In particular, when lever **650** is squeezed against an elongate body **630**, graspers **622***a* move outer housing **62** distally relative to inner housing **64** and connecting rod **10** to fully unlock connecting rod **10** from dual layered housing **60**. Upon fully unlocking connecting rod **10** from dual layered housing **60**, rod puller **700** may be utilized to remove connecting rod **10** from connecting rod slot **70** of inner housing **64** of bone screw **50**. Rod puller **700** includes a distal end portion **710** having a pair of spaced apart hook portions **722** configured and adapted to engage connecting rod **10**. In particular, hook portion **722** is coupled operatively with a rotating handle **750** to enable concomitant rotation therewith. Rotating handle **750** may be rotated to facilitate alignment of hook portion **722** with connecting rod **10**, as well as facilitating disengagement of rod **10** from connecting rod slot **70**. In this manner, the clinician may perform the unseating of connecting rod **10** from within connecting rod slot **70** of inner housing **64** of bone screw **50** through pulling of a handle member **707** when connecting rod **10** is engaged with hook portion **722**, as well as rotating rotating handle **750**.

With reference to FIGS. **22**-**24**, spinal stabilization system **100** may further include right and left in situ rod benders **800**, **820**, right and left coronal rod benders **900**, **920** and a tabletop rod bender **1200**. Right and left in situ rod benders **800**, **820** each define a slot **802**, **822**, respectively, for selective reception of connecting rod **10** therein. In particular, each slot **802**, **822** has a substantially rectangular wall **802***a*, **822***a* configured to engage elongate head portion **14** of connecting rod **10** in a single orientation. Right and left in situ rod benders **800**, **820** are configured for bending connecting rod **10** subsequent to placement of connecting rod **10** within the body. Right and left coronal rod benders **900**, **920** also each define a slot **902**, **922**, respectively, for selective reception of connecting rod **10** therein. Each slot **902**, **922** includes an arcuate end wall **902***a*, **922***a* configured to engage elongate rounded section **12** of connecting rod **10** in a single orientation. Right and left coronal rod benders **900**, **920** are configured for bending connecting rod **10** prior to placement of connecting rod **10** within the body. Table top bender **1200** includes a jaw mechanism **1220** configured and adapted for bending connecting rod **10**. Table top bender **1200** includes an alternative jaw mechanism (not shown) configured for cutting connecting rod **10**.

With reference to FIGS. **25-31**, spinal stabilization system **100** may further include a cross connector assembly **1000** configured to couple connecting rods **10** to each other. Cross connector assembly **1000** includes a pair of connectors **1020** and an intermediate portion **1050** connecting the pair of connectors **1020**. Each connector **1020** defines a recessed portion **1022** configured to be fixed securely to connecting rod **10**. In particular, each connector **1020** defines a slit **1024** configured to flex or enlarge the dimensions of recessed portion **1022** to facilitate insertion of connecting rod **10**. Recessed portion **1022** includes a substantially rectangular wall **1022***a* configured to engage elongate head portion **14** of connecting rod **10** and an opposing arcuate wall **1022***b* configured to engage elongate rounded section **12** of connecting rod **10**. In particular, recessed portion **1022** includes fingers **1022***c* to secure connecting rod **10** within recess portion **1022**.

In addition, each connector **1020** defines a bore **1026** (FIG. **29**) and a socket **1028** (FIG. **29**). Bore **1026** is configured and dimensioned to receive a screw **1044**. Socket **1028** is configured and dimensioned to receive a ball joint **1052**, **1054** of intermediate portion **1050**. Each connector **1020** further defines a slit **1032** configured to flex or enlarge socket **1028** to facilitate insertion of ball joint **1052**, **1054** of intermediate portion **1050** therein.

Upon insertion of connecting rod **10** in recessed portion **1022** and ball joint **1052**, **1054** in socket **1028**, screws **1044** are inserted into a respective bore **1026** to fix connecting rod **10** and ball joint **1052** in recessed portion **1022** and socket **1028**, respectively.

With particular reference now to FIG. **29**, intermediate portion **1050** includes an insertion arm **1060** and a receiving arm **1070**. Receiving arm **1070** defines a recessed portion **1072** configured and dimensioned to receive slidably insertion arm **1060** therein. Insertion arm **1060** defines a bore **1066** configured to receive a set screw **1033** to fix a relative position of arms **1060**, **1070**. In this manner, the length of intermediate portion **1060** may be adjustable by the clinician. Insertion arm **1060** and receiving arm **1070** include ball joint **1054**, **1052** configured to be received in socket **1028**. Under such a configuration, ball joints **1052**, **1554** enable variable or polyaxial adjustment between connector **1020** and intermediate portion **1050** prior to fastening of screw **1044**. As such, the length and orientation of intermediate portion **1050** relative to connector **1020** may be selectively chosen by the clinician prior to fastening set screw **1033** and screws **1044**.

With reference to FIG. **32**, spinal stabilization system **100** may further include a cross connector assembly **2000** configured to couple various connecting rods **10**, **11** to each other. For example, connecting rod **11** is a 5.5 mm diameter round rod. Connecting rod **10**, as described hereinabove, includes elongate rounded section **12** having a substantially circular cross-section, an elongate head portion **14**, and a neck portion **16** that connects and transitions elongate rounded section **12** into elongate head portion **14**, and thereby providing reduced stress concentration along the elongate body of connecting rod **10**.

Cross connector assembly **2000** includes connectors **2020**, **2030**. Connector **2020** defines a recessed portion **2022** configured to receive connecting rod **11** therein. Similar to connector **1020**, connector **2020** defines a slit **2024** configured to flex or enlarge the dimensions of recessed portion **2022** to facilitate insertion of connecting rod **11**. Recessed portion **2022** includes a pair of opposing fingers **2022***a* (only one shown) to secure connecting rod **10** within recess portion **2022**. In addition, connector **2020** defines a bore **2026** and a socket **2028**. Bore **2026** is configured and dimensioned to receive a screw **1044**. Socket **2028** is configured and dimensioned to receive a ball joint **2052** of connector **2030**. Connector **2020** further defines a slit **2032** configured to flex or enlarge socket **2028** to facilitate insertion of ball joint **2052** of connector **2030**.

Connector **2030** includes an elongate body **2035** having ball joint **2052** configured and dimensioned to be received in socket **2028** and a grasping portion **2070**. In particular, grasping portion **2070** defines a recess **2071** configured and dimensioned to receive at least a portion of elongate head portion **14** of connecting rod **10**. Recess **2071** has a substantially rectangular shape configured to engage elongate head portion **14** of connecting rod **10**. Moreover, recess **2071** defines a pair of opposing fingers **2071***a* that secures elongate head portion **14** within recess **2071**. In order to secure elongate head portion **14** between opposing fingers **2071***a*, connector **2030** may be made of a material that provides suitable flexibility to provide a snap-fit engagement with elongate head portion **14**. Alternatively, connector **2030** may be made of a rigid material in which case, one end of elongate head portion **14** may slide into recess **2071**.

In addition, connector **2030** further defines a bore **2075** configured and dimensioned to receive screw **1044** to fix connecting rod **10** to connector **2030**. Upon insertion of connecting rod **11** in recessed portion **2022** and ball joint **2052** of connector **2030** in socket **2028** of connector **2020**, screw **1044** is inserted into bore **2026** to fix connecting rod **11** in recessed portion **2022** and ball joint **2052** in socket **2028**. Similarly, screw **1044** is used to secure connecting rod **10** with connector **2030**. In this manner, cross connector assembly **2000** enables coupling of various connecting rods with various cross-sections and diameters.

With reference now to FIG. **33**, spinal stabilization system **100** may further include a cross connector assembly **3000** configured to couple connecting rods **10** to each other. Cross connector assembly **3000** includes an elongate body **3035** having a grasping portion **3070** at one end of elongate body **3035** and a grasping portion **3090** at another end of elongate body **3035**. The structure and method of using grasping portions **3070**, **3090** are substantially identical to grasping portion **2070**, as described hereinabove, and thus will not be described herein.

With reference now to FIGS. **34** and **34**A, spinal stabilization system **100** may further include an axial connector **4000**. Axial connector **4000** is configured to connect connecting rods **10**, **11** in a substantially linear fashion. However, the type of rods axial connector **4000** may connect are not limited to connecting rods **10**, **11**. Axial connector **4000** may be used to extend a rod construct that exists on the same side of the spinous process or to change rod diameter or type along the construct. Due to the deformity being corrected, it is sometimes beneficial to have different rod types to allow for a change in the type of correction needed. The axial connector **4000** is locked to the connecting rods **10**, **11** with screws **1044**.

With continued reference to FIGS. **34** and **34**A, axial connector **4000** includes an elongate body **4100** defining a longitudinal bore **4102**. The cross-section of longitudinal bore **4102** generally corresponds to the cross-section of connecting rod **10**. In this manner, both connecting rods **10**, **11** can be received through longitudinal bore **4102**. Moreover, elongate body **4100** further defines a plurality of bores **4045** configured and dimensioned to receive screws **1044** therein to fix connecting rods **10**, **11** to axial connector **4000**. As described above, it is contemplated that various connecting rods may be used with axial connector **4000**. For example, two connecting rods **10** may be used for a suitable construct, as shown in FIG. **35**.

With reference now to FIGS. **36** and **36**A, spinal stabilization system **100** may further include an offset connector **5000** to connect, for example, connecting rods **10**, **11**. Offset connector **5000** may typically be used to extend a rod construct that exists on the same side of the spinuous process or to change rod diameter or type along the construct. Due to the deformity being corrected, it is sometimes beneficial to have different rod types to allow for a change in the type of correction needed. Offset connector **5000** is locked to connecting rods **10**, **11** with set screws.

With continued reference to FIGS. **36** and **36**A, offset connector **5000** includes a body **5100**. Body **5100** includes a first connecting portion **5200** and a second connecting portion **5300** disposed adjacent first connecting portion **5200**. First connecting portion **5200** defines a bore **5250** configured and dimensioned to receive connecting rod **10** therethrough. First connecting portion **5200** further defines a hole **5109** to threadably receive screw **1044** to fix connecting rod **10** with first connecting portion **5200**. Second connecting portion **5300** defines a recess **5350** configured and dimensioned to receive connecting rod **11**. Recess **5350** may define an arcuate portion **5351** to accommodate connecting rods with circular cross-section. Preferably, recess **5350** has a depth greater than the diameter of connecting rod **11**, such that various diameter connecting rods may be accommodated in recess **5350**. The varying diameter of various connecting rods will be fixed securely in second connecting portion **5300** by screw **1044**. In addition, offset connector **5000** is not limited to the combination of connecting rods **10**, **11**. For example, a pair of connecting rods **10** may be used with offset connector **5000**, as shown in FIGS. **37** and **37**A.

With reference now to FIGS. **38** and **38**A, spinal stabilization system **100** may further include a spinal hook **6000**. Spinal hook **6000** may be used to connect the connecting rod to the anatomy in various locations. Some spinal hooks **6000** are used with the lamina, others with the pedicle. Spinal hook **6000** can also have a variety of sizes, shapes and angles to accommodate the anatomy. The spinal hook **6000** may be locked to connecting rod **10** with screw **1044**. Spinal hook **6000** includes a body **6100** and a hook **6150** extending therefrom. Body **6150** defines a recess **6200** configured and dimensioned to receive connecting rod **10** therein. The cross-section of recess **6200** generally corresponds to the cross-section of connecting rod **10**, which also accommodates round connecting rod **11**. As described above, it is contemplated that various connecting rods may be used with spinal hook **6000**. Screw **1044** is used to fix connecting rod **10** to spinal hook **6000**.

In use, two or more bone screws **50** are affixed to two or more vertebral bodies. Connecting rod **10** is then bent using one or more of the rod benders **80**, **800**, **820**, **900**, **920**, **1200** to conform connecting rod **10** to the configuration necessary to achieve proper alignment of the vertebral bodies. Once connecting rod **10** is appropriately bent, a clinician places connecting rod **10**, by hand, in alignment with dual layered housing **60** of bone screws **50** such that elongate rounded portion **12** is received within connecting rod slot **70** of dual layered housing **60** of bone screw **50**. Once connecting rod **10** is properly aligned with dual layered housing **60** of bone screw **50**, reduction device **200** is attached to dual layered housing **60** to seat connecting rod **10** within connecting rod slot **70** of bone screw **50**. Partial locker **300** is then placed over reduction device **200** and engaged with dual layered housing **60** of bone screw **50** to partially lock connecting rod **10** to dual layered housing **60**. Partial locker **300** and one or more reduction devices **200** are then disengaged from dual layered housing **60**. At this point, connecting rod **10** may be rotationally adjusted relative to dual layered housing **60** of bone screw **50**. In situ benders **800**, **820** may also be used to further bend connecting rod **10**. Upon proper orientation of connecting rod **10**, quick locker **500** is engaged with dual layered housing **60** of bone screw **50** to fully lock connecting rod **10** within dual layered housing **60** of bone screw **50**.

In the case of using more than one connecting rod **10**, **11**, cross connectors **1000**, **2000**, **3000**, axial connector **4000**, and/or offset connector **5000** may be utilized to further secure connecting rods **10**, **11** to vertebrae. Initially, a bone screw **50** is inserted into a pedicle and another is inserted into a pedicle of the same vertebral level on the opposite side of the spinous process. Two additional bone screws **50** are inserted into pedicles at a position cranial (or distal) to the first two screws **50** at the same vertebral level. A connecting rod **10**, **11** is inserted into two bone screws on one side of the spinous process and another connecting rod (of the same or different cross section or diameter) **10**, **11** is inserted into the two bone screws **50** on the opposite side of the spinous process. Bone screws **50** are locked and then a suitable cross connector **100**, **2000**, **3000** is attached to the two connecting rods **10**, **11** and locked into place. Spinal hook **6000** may be used as needed to provide additional stabilization.

Another method involves the construct above and in addition, the placement of axial connector **4000** at the distal end of both connecting rods **10**, **11**. Subsequent to the placement of axial connector **4000**, two more bone screws **50** are inserted into opposing pedicles at the same or different vertebral level. A connecting rod **10**, **11** (of the same or different diameter or cross section) is inserted into bone screws **50** and into axial connectors **4000**. Bone screws **50** are locked to connecting rods **10**, **11** and axial connectors **4000** are locked to connecting rods **10**, **11** to complete the construct. Alternatively, offset connector **5000** may be used.

With reference to FIGS. **39** and **40**, another embodiment of the present disclosure is shown generally as a spinal stabilization system **1000**. Spinal stabilization system **1000** includes at least one bone screw **50** and a connecting rod **500** releasably secured to bone screw **50**. Connecting rod **500** is configured and dimensioned to be selectively and releasably secured to bone screw **50**. Connecting rod **500** is defined by an elongate body of a particular length. The elongate body is made of a biocompatible material such as Titanium (Ti-CP) and its alloys (e.g., Ti-6Al-4V), Cobalt-Chrome Alloy (CoCr) or Stainless Steel (SS).

With particular reference to FIG. **39**, the elongate body of connecting rod **500** includes a first portion **510**, a second portion **570**, and a transition portion **550** that connects or transitions first portion **510** to second portion **570**. First portion **550** is substantially identical to connecting rod **10**. First portion **550** includes an elongate rounded section **512** having a substantially circular cross-section, an elongate head portion **514**, and a neck portion **516** that connects and transitions elongate rounded section **512** into elongate head portion **514**, and thereby providing reduced stress concentration along the elongate body of first portion **510**.

Elongate rounded section **512** of first portion **510** is configured and dimensioned to be received in connecting rod slot **70** of inner housing **64**. For example, rounded section **512** of first portion **510** may have a standard diameter of, for example, about 5.5 mm, suitable to mate with connecting rod slot **70**.

Elongate head portion **514** has a substantially rectangular cross-section having suitable dimensions of, for example, about 6 mm×about 1 mm (0.246 in.×0.039 in.). However, it is envisioned that elongate head portion **514** may have a cross-section that is substantially square, elliptical or any other shape to add rigidity to rounded section **512** of first portion **510**.

Neck portion **516** has dimensions that are smaller than those of elongate rounded section **512** and elongate head portion **514**. Neck portion **516** defines a pair of concave sides joining elongate head portion **514** to elongate rounded section **512**, so that the concave sides provide clearance for the taper lock screw housings.

Bone screw **50** may be positioned at any desired position along the elongate body of connecting rod **500**. When first portion **510** is secured to bone screw **50**, neck portion **516** of first portion **510** is disposed at the top of bone screw **50** and does not interfere with the interaction between first portion **510** and bone screw **50**. Furthermore, elongate head portion **514** of first portion **510** is disposed above the top of taper lock screw **50**.

With continued reference to FIG. **39**, transition portion **550** transitions first portion **510** to second portion **570**. Transition portion **550** is configured to reduced stress concentration along the elongate body of connecting rod **500**. In particular, transition portion **550** includes an elongate head portion **554**, an elongate rounded section **552** that is substantially identical to elongate rounded section **512** of first portion **510**, and a neck portion **556** that connects and transitions elongate rounded section **552** into elongate head portion **554**. In particular, transition portion **550** is longitudinally tapered such that an end portion thereof adjacent first portion **510** has a cross section that is substantially identical to a cross section of first portion **510** and an opposite end portion thereof adjacent second portion **570** has a cross section that is substantially identical to a cross section of second portion **570**. Second portion **570** includes a circular rod **600** concentrically aligned and coupled to elongate rounded section **552** of transition portion **550**. Circular rod **600** is configured and dimensioned to be received in connecting rod slot **70** of bone screw **50**.

First portion **510** provides a greater stiffness and rigidity than circular rod **600** of second portion **570**. Under such a configuration, a single body connecting rod **500** provides a non-uniform stiffness and rigidity. In addition, first and second portions **510**, **570** do not require any design changes to taper lock screw **50**, and thus advantageously provide efficiency of manufacture and inventory. The elongate body of connecting rod **500** may be monolithically formed as a unitary construct. For example, connecting rod **500** may be machined from a single piece of bar stock.

Although the illustrative embodiments of the present disclosure have been described herein with reference to the accompanying drawings, the above description, disclosure, and figures should not be construed as limiting, but merely as exemplifications of particular embodiments. For example, it is contemplated that elongate head portion **14** of connecting rod **10** need not extend over substantially the entire the elongate body of connecting rod **10**, but instead may only be provided in a portion of connecting rod **10** where it is desired to enhance the rigidity of that portion of the rod. One skilled in the art will recognize that the present disclosure is not limited to use in spine surgery, and that the instrument and methods can be adapted for use with any suitable surgical device. It is to be understood, therefore, that the disclosure is not limited to those precise embodiments, and that various other changes and modifications may be effected therein by one skilled in the art without departing from the scope or spirit of the disclosure.

What is claimed is:

1. A spinal stabilization system comprising:

a connecting rod including an elongate round portion, an elongate head portion including a planar surface, and a neck portion connecting the elongate round portion with the elongate head portion; and

a bone screw including a housing portion and a screw shaft extending distally from the housing portion, the housing portion including an inner housing and an outer housing slidably surrounding at least a portion of the inner housing, the inner housing defining a slot configured and dimensioned to releasably secure the elongate round portion of the connecting rod therein, wherein the outer housing is movable relative to the inner housing between an unlocked state in which the elongate round portion of the connecting rod is releasable from the slot defined in the inner housing and a locked state in which the connecting rod is secured in the slot, wherein a cross-section of the connecting rod is asymmetric about an axis of the connecting rod, and the elongate head portion extends away from the inner housing when the elongate round portion is disposed in the slot of the inner housing.

2. The spinal stabilization system according to claim **1**, wherein the elongate head portion of the connecting rod has a non-circular cross-section.

3. The spinal stabilization system according to claim **1**, wherein the elongate head portion of the connecting rod has a substantially rectangular cross-section.

4. The spinal stabilization system according to claim **1**, wherein the neck portion of the connecting rod has an arcuate profile.

5. The spinal stabilization system according to claim **4**, wherein the neck portion is narrower than the elongate round portion.

6. The spinal stabilization system according to claim **1**, wherein the connecting rod is monolithically formed.

7. The spinal stabilization system according to claim **1**, wherein the screw shaft is polyaxially coupled to the housing portion.

8. The spinal stabilization system according to claim **1**, wherein the outer housing includes a circumferentially disposed flange.

9. The spinal stabilization system of claim **1**, further comprising a plurality of bone screws.

10. The spinal stabilization system according to claim **1**, wherein the axis of the connecting rod extends through the neck portion.

11. The spinal stabilization system according to claim **10**, wherein the neck portion includes concave sides.

12. A spinal stabilization system comprising:

a bone screw including a housing defining a slot; and

a connecting rod including:

an elongate round section configured to be received in the slot of the bone screw;

an elongate head portion; and

a neck portion connecting the elongate round section to the elongate head portion, wherein the neck portion and the elongate head portion extend away from the housing when the elongate round section is disposed in the slot, wherein a cross-section of the connecting rod is asymmetric about an axis of the connecting rod, wherein the elongate head portion, the elongate round section, and the neck portion are formed as a unitary construct.

13. The spinal stabilization system according to claim **12**, wherein the housing includes an inner housing and an outer housing selectively positionable relative to the inner housing to lock the connecting rod in position within the slot defined by the inner housing.

14. The spinal stabilization system according to claim **13**, wherein the outer housing is transitionable relative to the inner housing between a locked position in which the connecting rod is fully locked in position within the inner housing and an unlocked position in which the connecting rod is movable within the inner housing, wherein the neck portion is configured to provide a space to permit transition of the outer housing between the locked and unlocked positions.

15. The spinal stabilization system according to claim **13**, wherein the neck portion is spaced apart from the inner housing when the elongate round section is disposed in the slot.

16. The spinal stabilization system according to claim **12**, wherein the elongate head portion has a non-circular cross-section.

17. The spinal stabilization system according to claim **12**, wherein the neck portion of the connecting rod has an arcuate profile.

18. The spinal stabilization system according to claim **12**, wherein the neck portion defines a pair of concave sides joining the elongate head portion to the elongate round section.

19. The spinal stabilization system according to claim **12**, wherein the elongate round section has a generally circular cross-section.

20. The spinal stabilization system according to claim **12**, wherein the neck portion is narrower than the elongate round section.

21. The spinal stabilization system according to claim **12**, wherein the elongate head portion, the elongate round section, and the neck portion are monolithically formed.

22. The spinal stabilization system according to claim **12**, wherein at least one of the elongate round section, the elongate head portion, or the neck portion is formed from a biocompatible material.

23. The spinal stabilization system according to claim **12**, wherein at least one of the elongate round section, the elongate head portion, or the neck portion is formed from a material selected from a group consisting of titanium, titanium alloy, cobalt-chrome alloy, and stainless steel.

24. The spinal stabilization system according to claim **12**, wherein the elongate head portion has a substantially rectangular cross-section.

25. A spinal stabilization system comprising:

a connecting rod including a first portion and a second portion, the first portion including an elongate round portion, an elongate head portion including a planar surface, and a neck portion connecting the elongate round portion with the elongate head portion, the second portion including a circular rod, the circular rod coupled to the elongate round portion; and

a bone screw including a housing portion and a screw shaft extending distally from the housing portion, the housing portion including an inner housing and an outer housing slidably surrounding at least a portion of the inner housing, the inner housing defining a slot configured and dimensioned to releasably secure the connecting rod therein, wherein the outer housing is movable relative to the inner housing between an unlocked state in which the connecting rod is releasable from the slot defined in the inner housing and a locked state in which connecting rod is secured to the slot, wherein a cross-section of the first portion of the connecting rod is asymmetric about an axis of the first portion, and the elongate head portion extends away from the inner housing when the elongate round portion is disposed in the slot of the inner housing.

26. The spinal stabilization system according to claim **25**, wherein the connecting rod further includes a transition portion connecting the first and second portions, the transition portion being longitudinally tapered.

27. The spinal stabilization system according to claim **26**, wherein the transition portion includes a first end having a cross section substantially identical to a cross section of the first portion and a second end having a cross section substantially identical to a cross section of the second portion.

28. The spinal stabilization system according to claim **27**, wherein the first end is adjacent the first portion and the second end is adjacent the second portion.

29. The spinal stabilization system according to claim **25**, wherein the connecting rod is monolithically formed.

30. A connecting rod for use in a spinal stabilization surgery, the connecting rod comprising:

an elongate rounded portion;

an elongate head portion having a non-circular cross-section; and

a neck portion connecting the elongate rounded portion with the elongate head portion, the neck portion having concave sides, wherein the neck portion has smaller dimensions than dimensions of the elongate rounded portion and the elongate head portion, wherein a cross-section of the connecting rod is asymmetric about an axis of the connecting rod, wherein the connecting rod is monolithically formed.

31. The spinal stabilization system according to claim **30**, wherein the elongate head portion of the connecting rod has a substantially rectangular cross-section.

32. The spinal stabilization system according to claim **30**, wherein the axis of the connecting rod extends through the neck portion.

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